Cardio Menu
Service Manual

AT-10

6-Channel Electrocardiograph

User`s Guide

Article Number 2.510276a

Associated Documents

Physician`s Guide to the Interpretation and Measurement Program
Article Number 2.510179

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DECLARATION OF CONFORMITY

Electrocardiograph:	AT-10
Serial numbers starting with:	171.
Year of manufacture:	1995 Onwards

We, the undersigned, hereby declare that the medical device (class IIa) specified above conforms with the essential requirement listed in Annex 1 of EC Directive 93/42/EEC.

This declaration is supported by:

Certificate of approval No:	11425-01 ISO 9001 (Rev.1994) EN 46001 by SQS
	45112-60-00 ISO 9001/08.94, EN 46001 / 12.93 by DEKRA
and	45112-16-00 Annex II, Section 3 of the Directive 93/42/EEC (30.04.1995)

CE 0124

Baar (Switzerland) 03.07.1996

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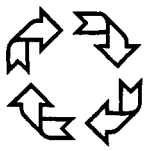
Terms of Warranty

WELCH ALLYN SCHILLER warrants the AT-10 Electrocardiograph, when new, to be free of defects in material and workmanship and to perform in accordance with manufacturer`s specifications for the period of three (3) years from the date of purchase from Welch Allyn or it`s authorized distributors or agents. Accessory items such as electrodes, batteries and cables are limited to a warranty of 90 days from the date of purchase from Welch Allyn or its authorized distributors or agents. Welch Allyn will repair or replace any components found to be defective or at variance from manufacturer`s specifications within this time at no cost to the customer. It shall be the purchasers responsibility to return the instrument to Welch Allyn or an authorized distributer, agent or service representative. This warranty does not include breakage or failure due to tampering, misuse, neglect, accidents, modifications or shipping. This warranty is also void if the instrument is not used in accordance with manufacturer`s recommendations or if repaired by other than Welch Allyn or an authorized agent. Purchase date determines warranty requirements. No other express warranty is given.

This equipment has been tested and found to comply with the limits for a class A digital device, pursuant to both Part 15 of the FCC (Federal Communications Commision) Rules and the radio interference regulations of the Canadian Department of Communications. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with this instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Disposal Instructions and Battery Care



- DO NOT DISPOSE OF THE BATTERY BY FIRE OR INCINERATOR - DANGER OF EXPLOSION
- DO NOT ATTEMPT TO RECHARGE THE BATTERY - DANGER OF EXPLOSION
- DO NOT OPEN THE BATTERY CASING - DANGER OF ACID BURN

Only dispose of the battery in official recycling centres or municipally approved areas. Alternatively used batteries can be returned to Schiller AG for disposal.

Unit Disposal Instructions

Units no longer required can be returned to Schiller AG for disposal. Alternatively dispose of the unit in municipally approved recycling centres.

Power Supply

The mains connection is on the rear of the unit.

The power supply voltage is set by the factory for100-115V(nom. 110V) or 220-240V (nom. 230V) working. The setting is indicated by the indented metal strip on the fuse panel. Contact your dealer if the voltage needs to be changed.

The mains indicator lamp on the keyboard is always lit when the unit is connected to the mains supply. The unit can either be operated from the mains supply or from the built-in rechargeable battery. The power source is indicted on the top line of the LCD.

Changing a Mains Fuse

If it is necessary to change a fuse, always replace with the correct rating i.e 2x200mAT for 230V, or 2x400mAT for 110V.

To change a fuse press the two retaining lugs on side of the fuse panel (situated below the mains connector on the back panel. Remove the fuse panel and replace the fuse(s). Click back the fuse panel.

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PHYSICIAN'S RESPONSIBILITY

THE AT-10 ELECTROCARDIOGRAPH IS PROVIDED FOR THE EXCLUSIVE USE OF QUALIFIED PHYSICIANS OR PERSONNEL UNDER THEIR DIRECT SUPERVISION. THE NUMERICAL AND GRAPHICAL RESULTS FROM A RECORDING MUST BE EXAMINED WITH RESPECT TO THE PATIENTS OVERALL CLINICAL CONDITION. THE RECORDING PREPARATION QUALITY AND THE GENERAL RECORDED DATA QUALITY, WHICH COULD EFFECT THE REPORT DATA ACCURACY, MUST ALSO BE TAKEN INTO ACCOUNT.

IT IS THE PHYSICIANS RESPONSIBILITY TO MAKE THE DIAGNOSIS OR TO OBTAIN EXPERT OPINION ON THE RESULTS, AND TO INSTITUTE CORRECT TREATMENT IF INDICATED.

FEDERAL LAW IN THE USA RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

Safety Notices

TO PREVENT ELECTRIC SHOCK DO NOT DISASSEMBLE THE UNIT. NO SERVICEABLE PARTS INSIDE. REFER SERVICING TO QUALIFIED PERSONNEL ONLY.

DO NOT USE THIS UNIT IN AREAS WHERE THERE IS ANY DANGER OF EXPLOSION OR THE PRESENCE OF FLAMMABLE GASES SUCH AS ANAESTHETIC AGENTS.

THIS PRODUCT IS NOT DESIGNED FOR STERILE USE.

THIS PRODUCT IS NOT DESIGNED FOR OUTDOOR USE.

SWITCH THE UNIT OFF BEFORE CLEANING AND DISCONNECT FROM THE MAINS.

DO NOT, UNDER ANY CIRCUMSTANCES, IMMERSE THE UNIT OR CABLE ASSEMBLIES IN LIQUID.

THE DEVICE MUST ONLY BE OPERATED USING BATTERY POWER IF THE EARTH CONNECTION IS SUSPECT OR IF THE MAINS LEAD IS DAMAGED OR SUSPECTED OF BEING DAMAGED.

DO NOT USE HIGH TEMPERATURE STERILISATION PROCESSES (SUCH AS AUTOCLAVING). DO NOT USE E-BEAM OR GAMMA RADIATION STERILISATION.

DO NOT USE SOLVENT CLEANERS

USE ONLY ACCESSORIES AND OTHER PARTS RECOMMENDED OR SUPPLIED BY WELCH ALLYN SCHILLER. USE OF OTHER THAN RECOMMENDED OR SUPPLIED PARTS MAY RESULT IN INJURY INACCURATE INFORMATION AND/ OR DAMAGE TO THE UNIT.

THE AT-10 COMPLIES WITH EMC REGULATIONS FOR MEDICAL PRODUCTS WHICH AFFORDS PROTECTION AGAINST EMISSIONS AND ELECTRICAL INTERFERENCE. HOWEVER SPECIAL CARE MUST BE EXERCISED WHEN THE UNIT IS USED WITH HIGH FREQUENCY EQUIPMENT.

IT MUST BE ENSURED THAT NEITHER THE PATIENT NOR THE ELECTRODES (INCLUDING THE NEUTRAL ELECTRODE) COME INTO CONTACT WITH OTHER PERSONS OR CONDUCTING OBJECTS (EVEN IF THESE ARE EARTHED).

THERE IS NO DANGER WHEN USING THE ECG UNIT FOR A ***PACEMAKER PATIENT*** *OR WITH SIMULTANEOUS USE OF OTHER ELECTRICAL STIMULATION EQUIPMENT. HOWEVER, THE STIMULATION UNITS SHOULD ONLY BE USED AT A SUFFICIENT DISTANCE FROM THE ELECTRODES. IN CASE OF DOUBT, THE PATIENT SHOULD BE DISCONNECTED FROM THE RECORDER.*

THIS UNIT IS CF CLASSIFIED ACCORDING TO IEC 601-1. THIS MEANS THAT THE PATIENT CONNECTION IS FULLY ISOLATED AND DEFIBRILLATION PROTECTED. WELCH ALLYN SCHILLER CAN ONLY GUARANTEE PROTECTION AGAINST DEFIBRILLATION VOLTAGE HOWEVER, WHEN THE ORIGINAL WELCH ALLYN SCHILLER PATIENT CABLE IS USED.

IF SEVERAL UNITS ARE COUPLED THERE IS A DANGER OF SUMMATION OF LEAKAGE CURRENT

DO NOT TOUCH THE CASING DURING DEFIBRILLATION

IF THE PATIENT CABLE SHOULD BECOME DEFECTIVE AFTER DEFIBRILLATION, LEAD OFF WILL BE DISPLAYED AND AN ACOUSTIC ALARM GIVEN

AT-10 User`s Guide

This User`s Guide gives instructions on how to operate the unit and provides an overview of all the basic functions in an easy and simple to use format. The procedures are presented in a logical, step-by step way to enable the user to quickly and easily familiarise themselves with unit operation. Detailed medical information is excluded from this guide except where necessary to operate the unit or understand the results.

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CE 0124 93/42/EEC Medical Devices:
0124 `Notified Body` DEKRA AG

CHAPTER 1

Introduction and System Settings

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INTRODUCTION

The SCHILLER AT-10 is a technologically advanced, compact unit for cardiovascular and lung function diagnosis with the following features:

- Low weight and mains independent operation for portability.
- Large, clear and bright LCD display for the simultaneous monitoring of up to 8 leads.
- Simple menu guidance and direct function keys for ease of operation.
- Intergrated thermal printer combined with several print functions and formats to ensure clear and precise documention of the data.
- Video interface for the connection of an external video monitor and two DC input connections for on-screen presentation or printout of external signals.
- Three RS-232 interfaces and one RS-422 interface for
  - automatic ergometer control (bicycle or treadmill)
  - the connection of an external blood pressure measuring unit
  - data transmission/reception
- Resting ECG and exercise ECG as standard software options.
- Optional software for ECG measurement and interpretation, evaluation of exercise ECGs, pacemaker measurement, heart rate variability, late potential analysis.
- Optional software for spirometry testing with or without respiratory resistance measurement.
- Integration with SEMA - SCHILLER's data management system for verification and archiving of recorded data.

Location

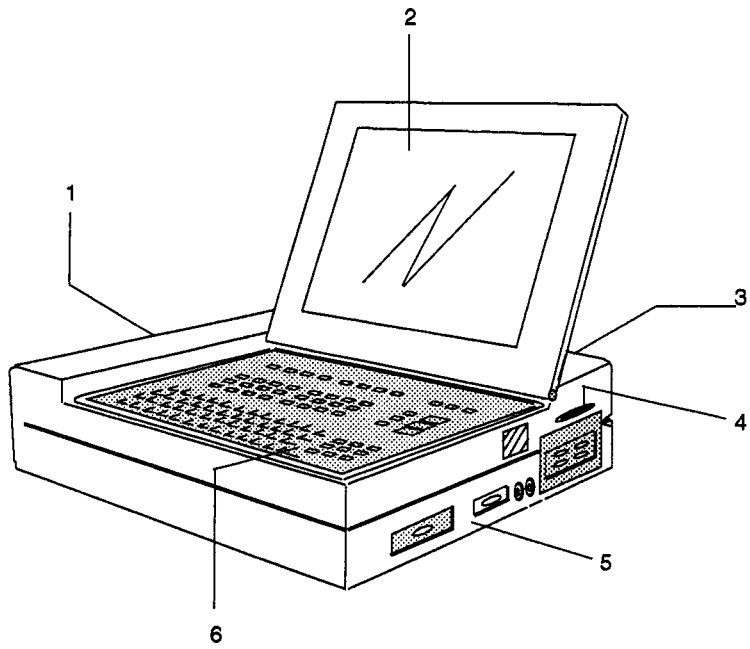
- Do not keep or operate the unit in a wet, moist, or dusty environment. Avoid exposure to direct sunlight or heat from other sources.
- Do not allow the unit to come into contact with acid vapours or liquids.
- The AT-10 should not be placed in the vicinity of X-ray or diathermy units, large transformers or electric motors. It must also be positioned at least one meter from the mains supply.

Potential Equalisation

The potential equalisation connector (provided at the rear of the unit) is marked with the symbol ⏚. The yellow/green ground cable supplied as an option (Art. No. 2.310005) fits to the connector.

Using this connector, the ECG unit may be linked to the potential equalization connector of other mains powered equipment to ensure that all instruments are at the same earth potential.

MAIN PARTS OF THE UNIT



1 Integrated thermal printer with paper tray
Paper tray extends and retracts automatically at the press of a button.

2 Large, clear, tilt-up LCD screen

3 Back panel with

- mains connector and power switch
- potential equalisation stud
- interface for external video monitor
- exercise testing interface
- Data I/O socket (QRS-trigger output, footswitch)
- optional LAN connector (Local Area Network)

4 LCD contrast control

5 Side panel with

- 4 serial interfaces (3x RS-232, 1x RS-422)
- 2 DC inputs 0,5 V/cm
- optional connector for flow sensor (for lung function testing)
- patient cable input

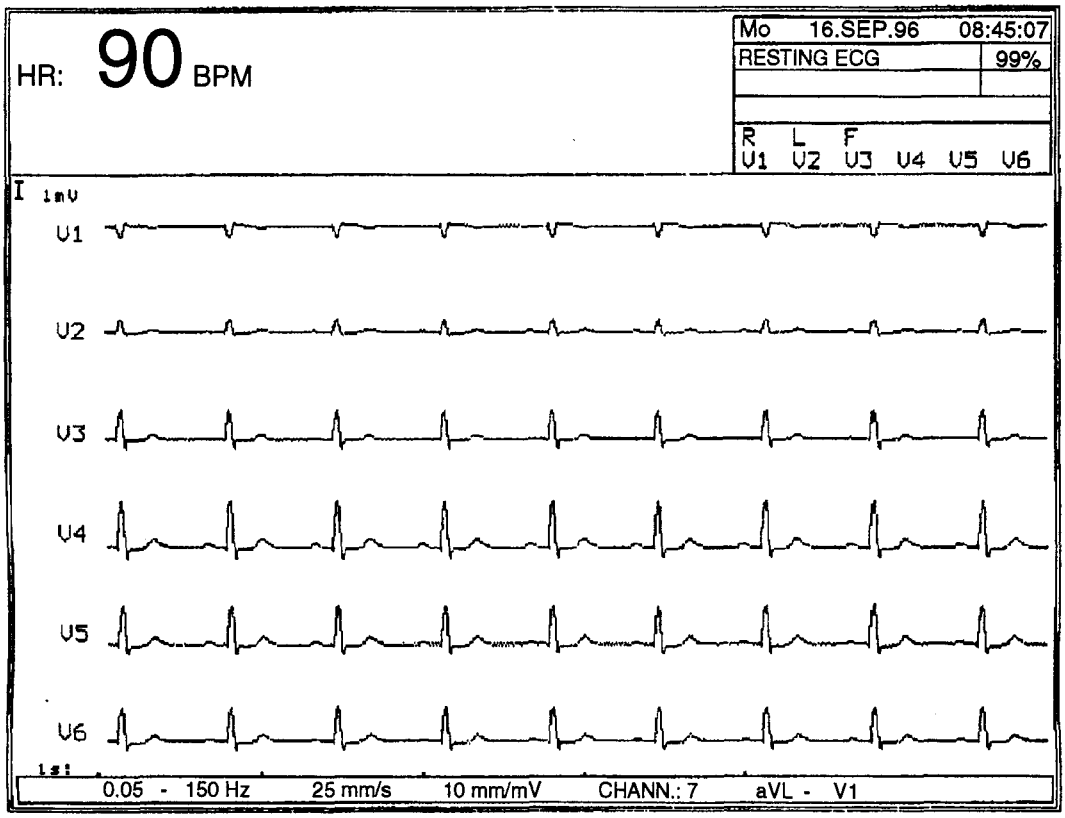
6 Waterproof keypads

LIQUID CRYSTAL DISPLAY (LCD)

Screen Overview

The "resting ECG" mode is automatically selected each time the unit is switched on.

The ECG signals are acquired, processed and displayed on the screen as shown in the example below. With no patient cable connected, the same display appears, however, without the ECG traces.



Top Part of Screen

Status and operating information are permanently displayed in the top section of the screen. The left side displays the heart rate (HR) and specific measurement data (when recording an ECG in automatic mode). The right side is divided into the following fields (from top to bottom):

- date and time
- mode of operation and, next right, remaining battery capacity as % of full battery capacity
- message field (this displays any status or error messages)
- status of capital letter lock ("CAPS" indicates capital letter lock on)
- lead status (if a "LEAD OFF" status is detected, an audible alarm will be given and the electrode indication flashes)

NOTE: When this happens, reapply the electrode (see Chapter 2).

LIQUID CRYSTAL DISPLAY (LCD)

Central Section

The central section of the screen is taken up with the measured ECG traces. The lead identifications are given on the left-hand side. In the left-hand corner is the 1 mV reference mark.

The time reference is given below the bottom lead indicated by "1 s" and a series of points; the time difference from point to point is 1 second.

Bottom Section

The bottom line of the LCD gives, from left to right

- selected baseline and myogram filter settings
- speed in "mm/s" for printing in manual mode
- sensitivity in "mm/mV" for printing in manual mode
- number of channels and selected leads for printing in manual mode

Contrast Adjustment

The contrast can be adjusted by means of the LCD knob located on the right-hand side of the unit.

KEYBOARD

Alphanumeric Keys

DUAL PURPOSE KEYS	
KEY	FUNCTION
`1´ to `7´	Printout Speed Selection 2.5, 5, 10, 12.5, 25, 50 or 100 mm/s Macro Function Keys (1-6)
`8´ to `_´	Printout Sensitivity Selection 2.5, 5, 10, or 20 mm/mV

KEYBOARD KEYS	
KEY	FUNCTION
DELETE	Delete character to the left of the cursor.
ENTER	Confirm entry or selection.
SPACE	Enter blank space into the text.
SHIFT	When pressed simultaneously with a letter key it activates the upper case letter. When pressed simultaneously with a number key it activates an alternative symbol set.
CAPS LOCK	Toggle key to set lower case or upper case letters. The Caps Lock key status is indicated on status information field on the right-hand side of the screen.

ON/OFF Keys

I ON — switch unit on

O OFF — switch unit off

Replace Paper Key

REPLACE PAPER — extend or retract the paper tray for paper replacement

Direct Function Keys

PATIENT DATA — input of patient data

SEND DATA — initiate data transmission to another unit

STORE DATA — initiate data storage to internal memory

RECEIVE DATA — initiate data reception from another unit

MEMORY — display menu for data storage and transmission

CHANGE SCREEN — toggle display

PRINT SCREEN — print the displayed screen

COPY — initiate copy of last ECG recording

2ND — select second function

KEYBOARD

Control Keys

AUTO START — start automatic recording and printing

MAN START — start manual recording and printing

STOP — stop manual recording and printing / advance paper to beginning of new page

FNCT — display menu for system settings / return to monitor mode

ESC — return to previous menu

NO – — change setting / disable function

YES + — change setting / enable function

◁ — move cursor to the left

▷ — move cursor to the right

△ — move cursor or menu bar up

▽ — move cursor or menu bar down

KEYBOARD

ECG Function Keys

ECG	select resting ECG menu
LEAD ◁	select previous lead group (for display and printout)
LEAD ▷	select next lead group (for display and printout)
MONITOR mm/s	select display speed
MONITOR mm/mV	select signal level for display
MONITOR CHANNEL	select number of channels (3, 6, 8) for the display
⋈	reset ECG signal to baseline
FILTER	switch myogram filter on or off
1 mV	insert calibration signal on the screen or on the printout
PRINTER CHANNEL	select number of channels (3, 6 and programmable number) for printout

KEYBOARD

Exercise ECG Function Keys

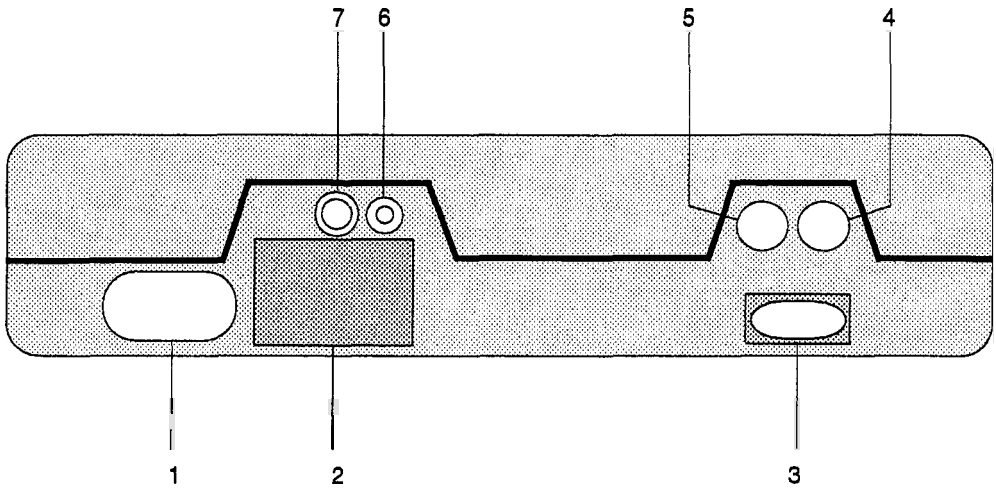
EXERCISE	select menu for exercise ECG
PROTOCOL	display/select exercise protocol
SYMPTOMS	manual input of symptoms
BEGIN TEST	start exercise test (beginning of warm-up phase)
RECOVERY	stop exercise test (start of recovery phase)
PRINT REPORT	print final report (end of recovery phase)
PRINT RHYTHM	print rhythm strip
HOLD STAGE	hold current load stage
NEXT STAGE	switch to next load stage
GRADE	increase or decrease treadmill elevation in combination with the YES + and NO − keys
SPEED / LOAD	increase or decrease speed (treadmill) or load (bicycle) in combination with the YES + and NO − keys

Further Function Keys

NIBP	select menu for non-invasive blood pressure measurements
SPIRO	select spirometry menu (if installed)

EXTERNAL CONNECTIONS

Rear Panel



1 Unit identification plate

2 **Mains connector with** power switch and mains fuse box (fuses: 2 x T 200 mA / 250 V)

3 Connector for external video monitor

4 Exercise test connection for analogue ergometer (bicycle or treadmill)

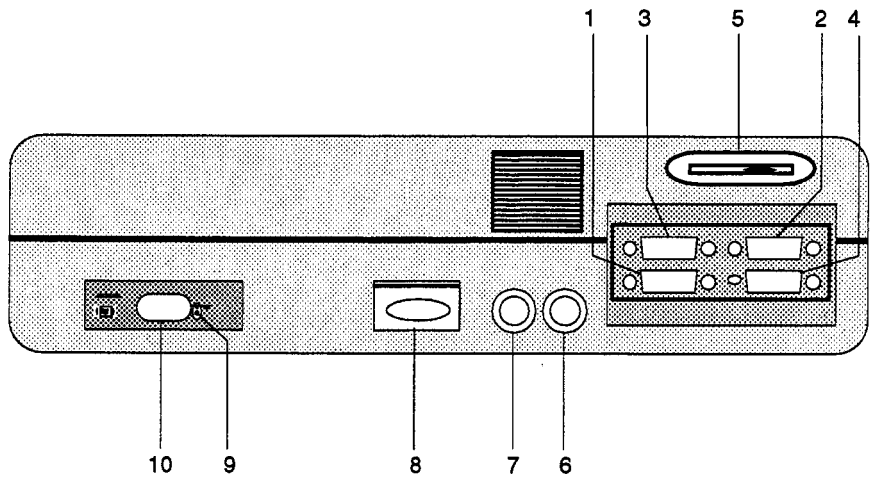
5 Data I/O socket for connection of footswitch (option), QRS trigger, treadmill elevation control

6 Potential equalisation stud

7 **Optional LAN connector** (Local Area Network)

EXTERNAL CONNECTIONS

Side Panel



1 RS-232C interface (port 1) for connection of a blood pressure device

2 RS-232C interface (port 2) for connection of an ergometer (bicycle or treadmill)

3 RS-232C interface (port 3) for data transfer

4 RS-422 interface for data transfer

5 LCD contrast control

6 DC input DCIN 1, 0.5 V/cm

7 DC input DCIN 2, 0.5 V/cm

8 Connector for pneumotach sensor SP-110, SP-110/R, SP-150 or SP-20 for pulmonary function testing

9 TEST = test socket for patient cable with control light

10 EKG/ECG = patient cable input socket

-> **CF rated**
The socket is CF rated, that is fully floating and isolated, defibrillation protected, suitable for intra-cardiac application.

CAUTION!

DEFIBRILLATION PROTECTED ONLY IF USED WITH ORIGINAL WELCH ALLYN SCHILLER PATIENT CABLE !

MENU STRUCTURE

Introduction

All test functions, setup definitions, and operations are carried out at the press of a key via the simple window menu structure. To call up a menu for any function, simply select the menu and press the respective function key or when the menu is highlighted, press the **ENTER** key.

To select a menu, either press either the ▽ or △ key and confirm with **ENTER**, or simply press the appropriate number key.

The main function keys lead to many selection possibilities. The structure of those "trees" are logically formed and an overview is shown on the following pages.

Leaving a menu is the same for all displays:

- With the ESC key you return to the previous menu.
- With the FNCT key you leave the menu structure completely and return to the main display.

NOTE: *Certain menu positions that are shown in the following overviews are only available if the appropriate software option is installed.*

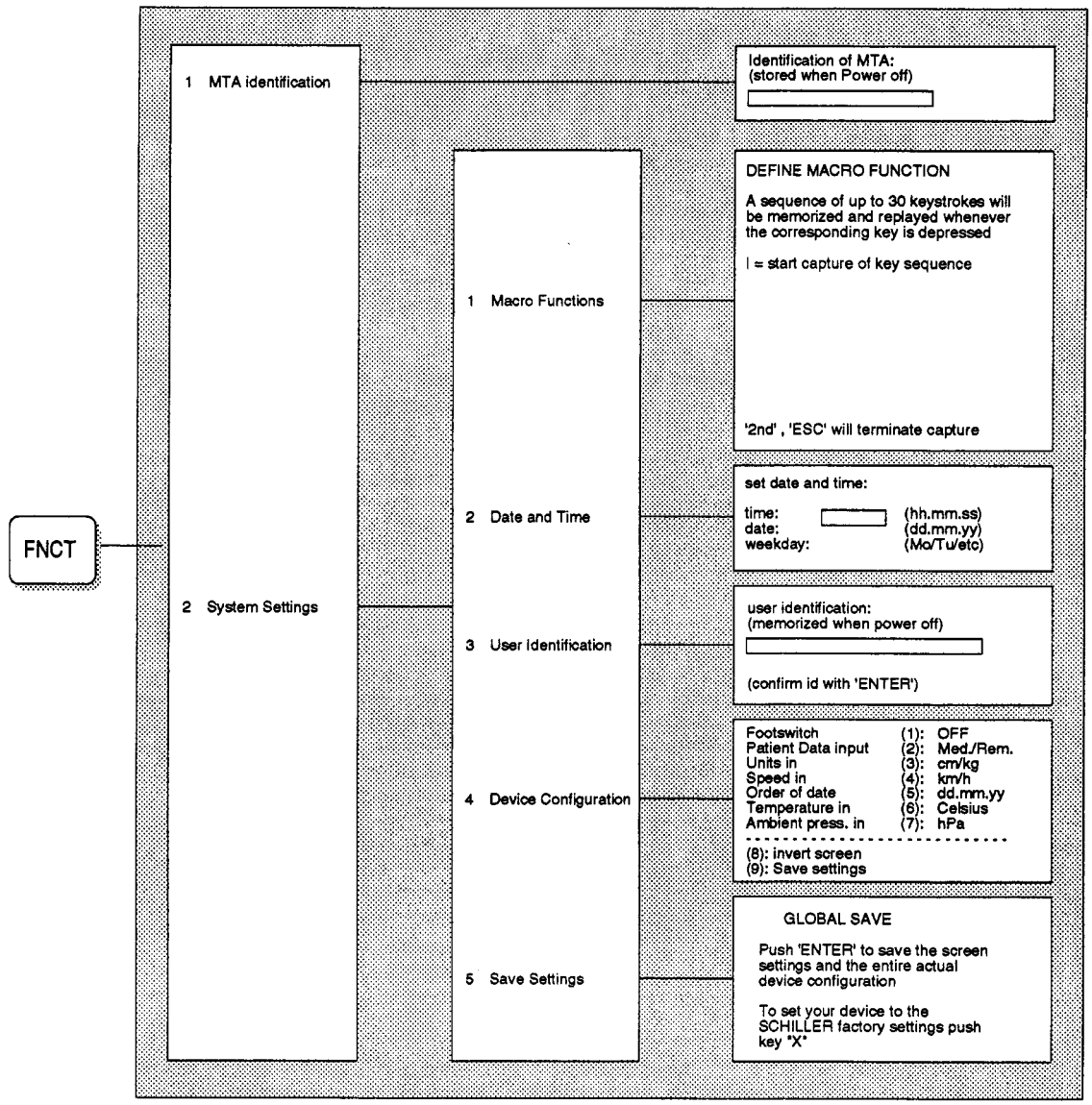
If an option is not installed, the following message appears:

Selected Function not Available (Corresponding Option Required)

MENU STRUCTURE

FNCT Menu

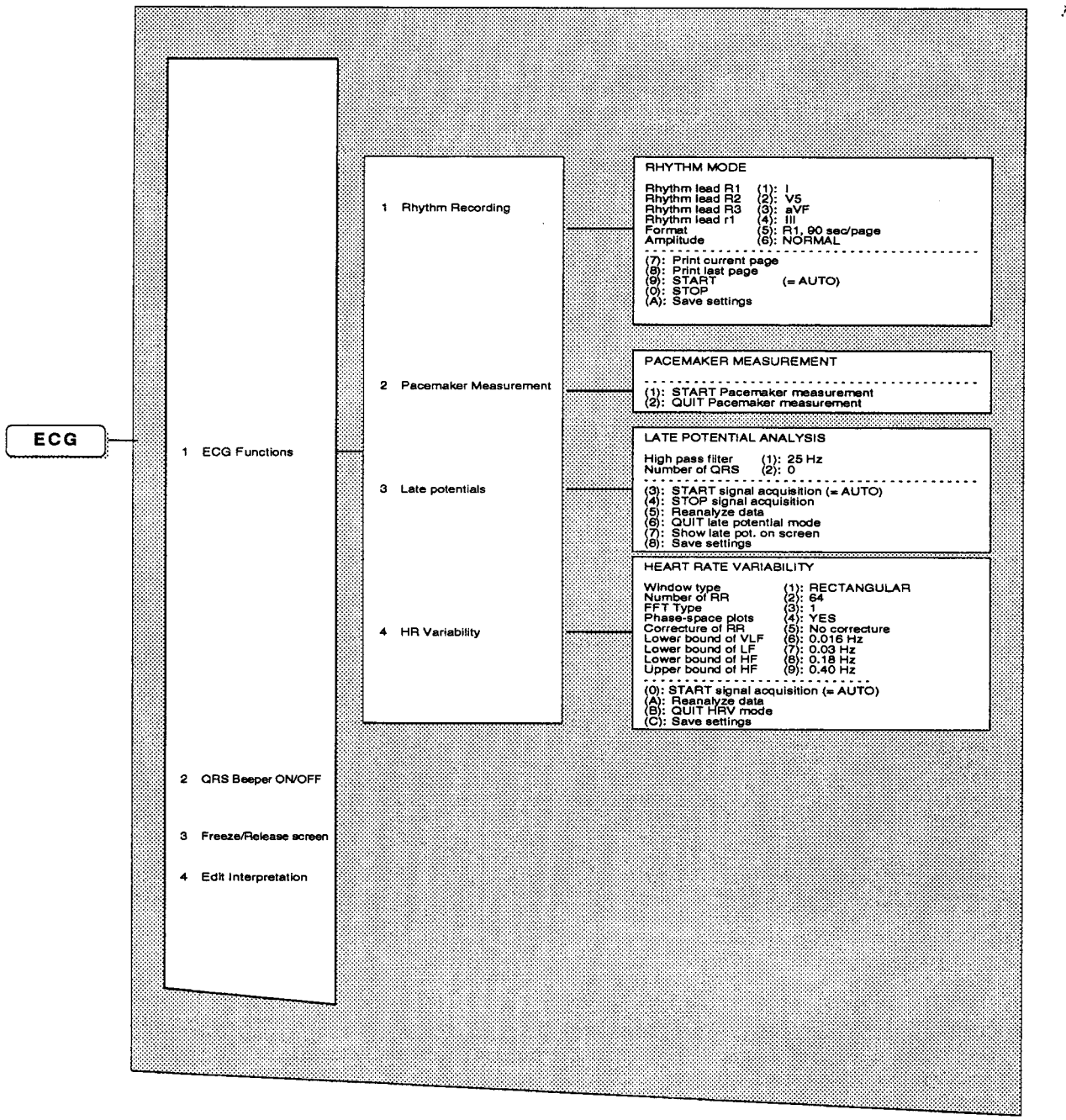
NOTE: *Certain menu positions that are shown in the following overview are only available if the appropriate software option is installed.*


FNCT
1 MTA identification
2 System Settings
1 Macro Functions
2 Date and Time
3 User Identification
4 Device Configuration
5 Save Settings
Identification of MTA:
(stored when Power off)
DEFINE MACRO FUNCTION
A sequence of up to 30 keystrokes will be memorized and replayed whenever the corresponding key is depressed
I = start capture of key sequence
'2nd' , 'ESC' will terminate capture
set date and time:
time: (hh.mm.ss)
date: (dd.mm.yy)
weekday: (Mo/Tu/etc)
user identification:
(memorized when power off)
(confirm id with 'ENTER')
Footswitch (1): OFF
Patient Data input (2): Med./Rem.
Units in (3): cm/kg
Speed in (4): km/h
Order of date (5): dd.mm.yy
Temperature in (6): Celsius
Ambient press. in (7): hPa
(8): invert screen
(9): Save settings
GLOBAL SAVE
Push 'ENTER' to save the screen settings and the entire actual device configuration
To set your device to the SCHILLER factory settings push key "X"

MENU STRUCTURE

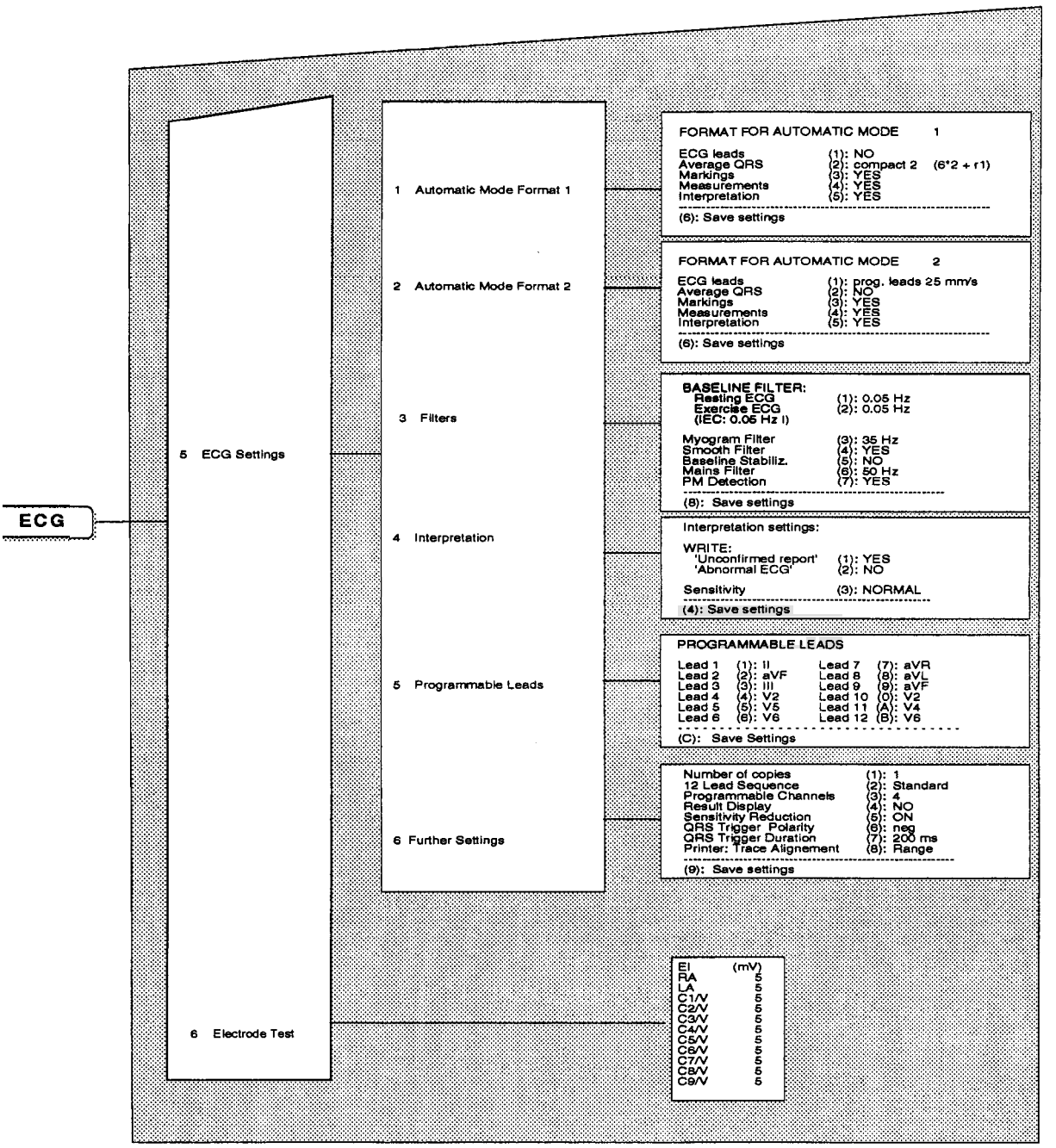
ECG Menu

NOTE: *Certain menu positions that are shown in the following overview are only available if the appropriate software option is installed.*


ECG
1 ECG Functions
2 QRS Beeper ON/OFF
3 Freeze/Release screen
4 Edit Interpretation
1 Rhythm Recording
2 Pacemaker Measurement
3 Late potentials
4 HR Variability
RHYTHM MODE
Rhythm lead R1 (1): I
Rhythm lead R2 (2): V5
Rhythm lead R3 (3): aVF
Rhythm lead r1 (4): III
Format (5): R1, 90 sec/page
Amplitude (6): NORMAL
(7): Print current page
(8): Print last page
(9): START (= AUTO)
(0): STOP
(A): Save settings
PACEMAKER MEASUREMENT
(1): START Pacemaker measurement
(2): QUIT Pacemaker measurement
LATE POTENTIAL ANALYSIS
High pass filter (1): 25 Hz
Number of QRS (2): 0
(3): START signal acquisition (= AUTO)
(4): STOP signal acquisition
(5): Reanalyze data
(6): QUIT late potential mode
(7): Show late pot. on screen
(8): Save settings
HEART RATE VARIABILITY
Window type (1): RECTANGULAR
Number of RR (2): 64
FFT Type (3): 1
Phase-space plots (4): YES
Correcture of RR (5): No correcture
Lower bound of VLF (6): 0.016 Hz
Lower bound of LF (7): 0.03 Hz
Lower bound of HF (8): 0.18 Hz
Upper bound of HF (9): 0.40 Hz
(0): START signal acquisition (= AUTO)
(A): Reanalyze data
(B): QUIT HRV mode
(C): Save settings

MENU STRUCTURE

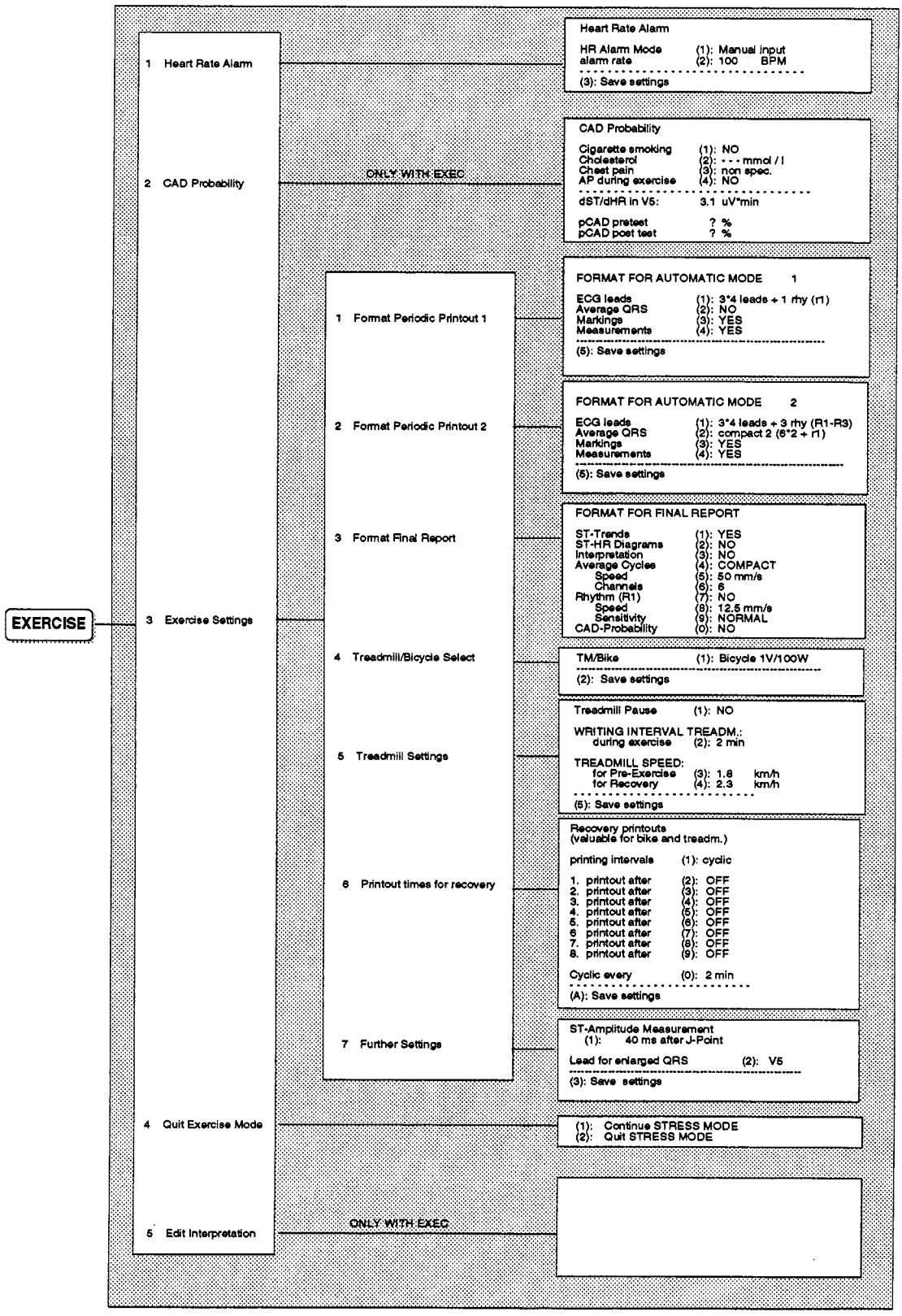
ECG Menu (Cont.)



MENU STRUCTURE

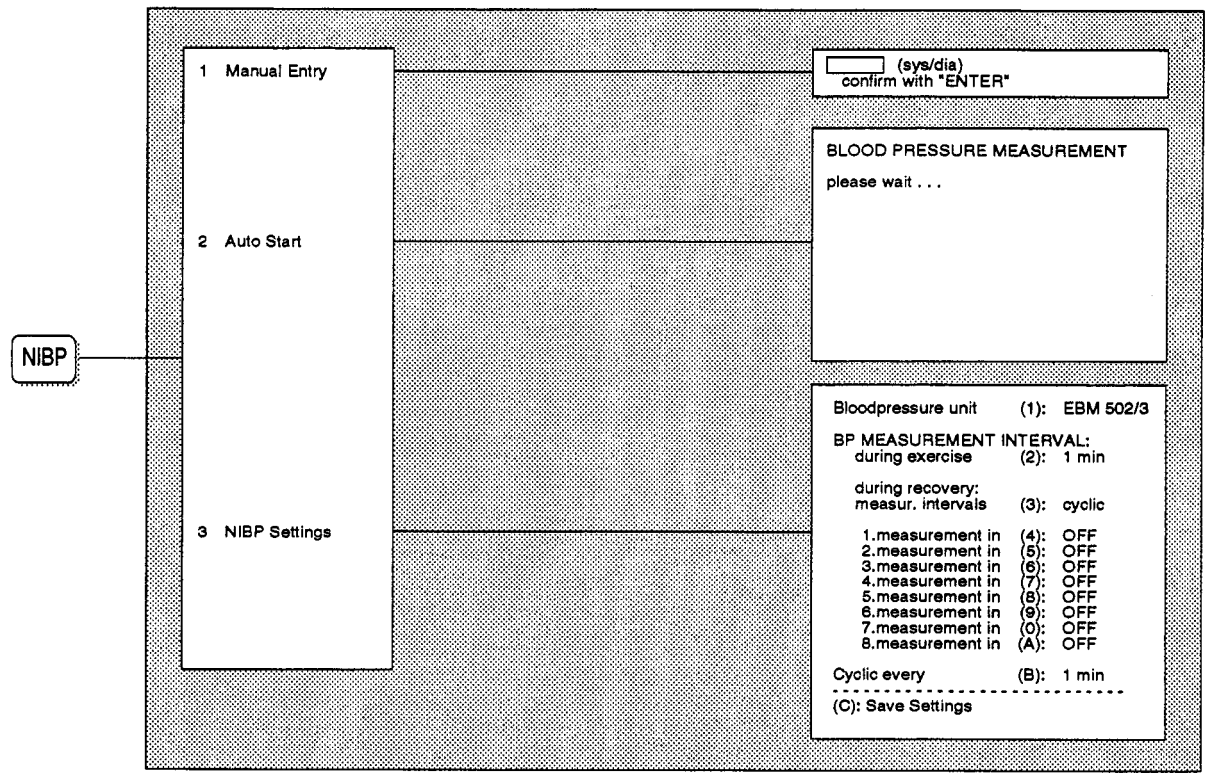
EXERCISE Menu

NOTE: Certain menu positions that are shown in the following overview are only available if the appropriate software option is installed.


EXERCISE
1 Heart Rate Alarm
2 CAD Probability
3 Exercise Settings
4 Quit Exercise Mode
5 Edit Interpretation
ONLY WITH EXEC
ONLY WITH EXEC
1 Format Periodic Printout 1
2 Format Periodic Printout 2
3 Format Final Report
4 Treadmill/Bicycle Select
5 Treadmill Settings
6 Printout times for recovery
7 Further Settings
Heart Rate Alarm
HR Alarm Mode (1): Manual input
alarm rate (2): 100 BPM
(3): Save settings
CAD Probability
Cigarette smoking (1): NO
Cholesterol (2): - - - mmol / l
Chest pain (3): non spec.
AP during exercise (4): NO
dST/dHR in V5: 3.1 uV*min
pCAD pretest ? %
pCAD post test ? %
FORMAT FOR AUTOMATIC MODE 1
ECG leads (1): 3*4 leads + 1 rhy (I1)
Average QRS (2): NO
Markings (3): YES
Measurements (4): YES
(5): Save settings
FORMAT FOR AUTOMATIC MODE 2
ECG leads (1): 3*4 leads + 3 rhy (R1-R3)
Average QRS (2): compact 2 (6*2 + I1)
Markings (3): YES
Measurements (4): YES
(5): Save settings
FORMAT FOR FINAL REPORT
ST-Trends (1): YES
ST-HR Diagrams (2): NO
Interpretation (3): NO
Average Cycles (4): COMPACT
Speed (5): 50 mm/s
Channels (6): 6
Rhythm (R1) (7): NO
Speed (8): 12.5 mm/s
Sensitivity (9): NORMAL
CAD-Probability (0): NO
TM/Bike (1): Bicycle 1V/100W
(2): Save settings
Treadmill Pause (1): NO
WRITING INTERVAL TREADM.:
during exercise (2): 2 min
TREADMILL SPEED:
for Pre-Exercise (3): 1.8 km/h
for Recovery (4): 2.3 km/h
(5): Save settings
Recovery printouts
(valuable for bike and treadm.)
printing intervals (1): cyclic
1. printout after (2): OFF
2. printout after (3): OFF
3. printout after (4): OFF
4. printout after (5): OFF
5. printout after (6): OFF
6. printout after (7): OFF
7. printout after (8): OFF
8. printout after (9): OFF
Cyclic every (0): 2 min
(A): Save settings
ST-Amplitude Measurement
(1): 40 ms after J-Point
Lead for enlarged QRS (2): V5
(3): Save settings
(1): Continue STRESS MODE
(2): Quit STRESS MODE

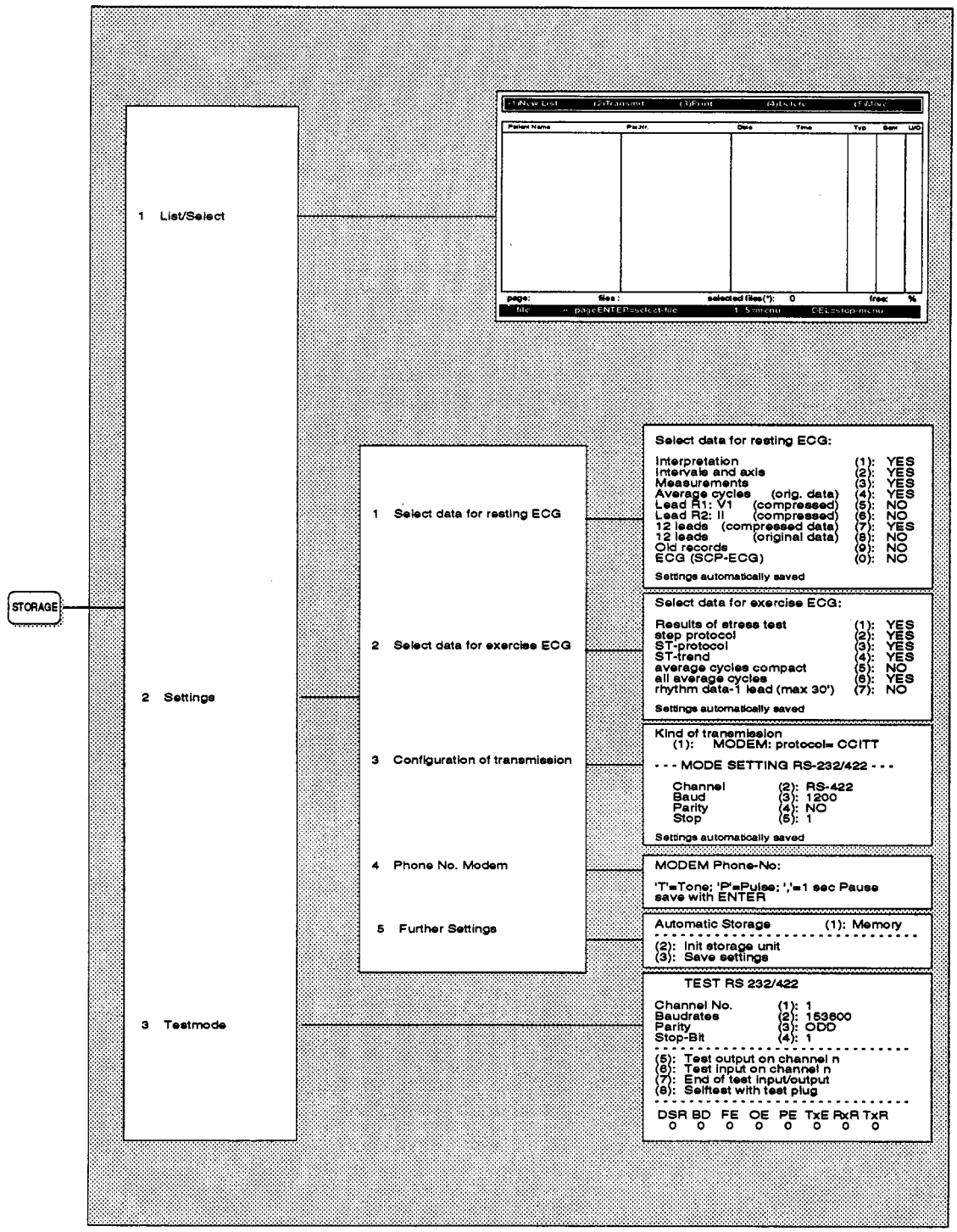
MENU STRUCTURE

NIBP Menu



MENU STRUCTURE

STORAGE Menu


STORAGE
1 List/Select
2 Settings
3 Testmode
1 Select data for resting ECG
2 Select data for exercise ECG
3 Configuration of transmission
4 Phone No. Modem
5 Further Settings
Select data for resting ECG:
Interpretation (1): YES
Intervals and axis (2): YES
Measurements (3): YES
Average cycles (orig. data) (4): YES
Lead R1: V1 (compressed) (5): NO
Lead R2: II (compressed) (6): NO
12 leads (compressed data) (7): YES
12 leads (original data) (8): NO
Old records (9): NO
ECG (SCP-ECG) (0): NO
Settings automatically saved
Select data for exercise ECG:
Results of stress test (1): YES
step protocol (2): YES
ST-protocol (3): YES
ST-trend (4): YES
average cycles compact (5): NO
all average cycles (6): YES
rhythm data-1 lead (max 30') (7): NO
Settings automatically saved
Kind of transmission
(1): MODEM: protocol= CCITT
- - - MODE SETTING RS-232/422 - - -
Channel (2): RS-422
Baud (3): 1200
Parity (4): NO
Stop (5): 1
Settings automatically saved
MODEM Phone-No:
'T'=Tone; 'P'=Pulse; ','=1 sec Pause
save with ENTER
Automatic Storage (1): Memory
(2): Init storage unit
(3): Save settings
TEST RS 232/422
Channel No. (1): 1
Baudrates (2): 153600
Parity (3): ODD
Stop-Bit (4): 1
(5): Test output on channel n
(6): Test input on channel n
(7): End of test input/output
(8): Selftest with test plug
DSR BD FE OE PE TxE RxR TxR
0 0 0 0 0 0 0 0

BASIC SYSTEM SETTINGS

Unit Configuration

Press the following keys to enter the unit configuration menu and set the menu options to your preference:

The possible selections are:

Footswitch operation — Press key **1** and set to:
- ON (footswitch connected)
- OFF (no footswitch connected)

Patient Data input — Press key **2** and set additional lines in the patient data input menu as:
- Room/Doc. (Room No. / Doctors Name)
- Room/Rem. (Room No. / Remarks)
- Doc./Rem. (Doctors Name / Remarks)
- Med./Rem. (Medication / Remarks)
- Med./Doc. (Medication / Doctors Name)
- Med./Room (Medication / Room No.)

(additional details to appear in the patient data explanations)

Units in — Press key **3** and set the calculating units to:
- cm and kg
- inch and lb

Speed in — Press key **4** and set the speed for exercise device to:
- km/h
- m.p.h

Date format — Press key **5** and set the input possibility to:
- dd.mm.yy (Day / Month / Year)
- mm-dd-yy (Month / Day / Year)

Temperature — Press key **6** and set to :
- Celsius
- Fahrenheit

Ambient pressure — Press key **7** and set to :
- mmHg
- hPa

Invert screen — Press key **8** to select positive or negative screen image

To save the settings made, press key **9**. Confirmation is given by the indication

* * * Settings memorized! * • •

BASIC SYSTEM SETTINGS

Set Date and Time

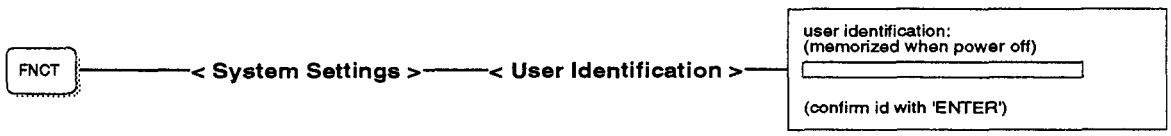
Set the date and time on the unit as follows:

Type in the new time, date and weekday and confirm each entry by pressing the **ENTER** key.

Exit the menu by pressing FNCT or ESC

User Identification

This function enables the entry of the name of either the physician, clinic or department. That name is then identified on each ECG printout. The menu is reached as follows:



The maximum number of characters for entry is 31.

By pressing **ENTER** the setting will be permanently stored and confirmation is given by the message ** Input accepted **.

Store Unit Settings

The current screen and device configuration can be stored as follows:

Confirm the settings with ENTER and they will remain active until changed (even if the unit is switched off).

Default Settings

To reset all settings to the default press key X . This is confirmed by an acoustic signal. On the screen the indication '* * *' is given.

ECG SETTINGS

The ECG settings menu comprises a sub-menu for common ECG settings. It is reached as follows:

Number of printouts

Your AT-10 can be programmed to automatically provide additional copies of each Auto ECG after you print it initially.

Press key **1** and select "Number of copies" in order to define the number of copies or prevent the automatic printout. If no printout is required, select 0 here. Otherwise between 1 to 4 copies can be defined.

12 Lead Sequence

This sets the lead sequence for manual and auto printouts as well as on the screen. With key **2** the lead sequence is set to either "Standard" or "Cabrera".

Standard				Cabrera			
I	aVR	V1	V4	aVL	II	V1	V4
II	aVL	V2	V5	I	aVF	V2	V5
III	aVF	V3	V6	-aVR	III	V3	V6

To change the displayed group of leads on the screen (or manual printout), press the lead key LEAD ◁ or LEAD ▷ until the new lead group appears.

Programmable Channels

The number of channels that can be printed in manual mode or for the programmed leads in automatic mode are 3 or 6 (the number of channels printed is changed by pressing the PRINTER CHANNEL key) .With key **3** a user-defined amount of channels can be set.

Select between: 4, 5 or 7

Result Display

Average QRS cycles can be displayed immediately after the evaluation of an ECG in automatic mode. Press key **4** and set to "YES" to permit this function.

ECG SETTINGS

Sensitivity Reduction

All leads are recorded with the sensitivity of 10 mm/mV unless the amplitudes are too high which would mean that the QRS peaks would overlap too much; in this case the sensitivity is reduced automatically to 5 mm/mV.

With key **5,** automatic **sensitivity reduction** can be switched ON or OFF.

The switching on or off of the automatic sensitivity adjustment affects only the presentation of the leads on the automatic ECG printout (resting and exercise ECG).

QRS Trigger Polarity

For every heartbeat a trigger pulse is emitted via the DATA I/O socket at the rear of the unit. This pulse can be recorded with an external unit.

Key **6** sets the polarity of the QRS trigger pulse to POS or NEG.

-

The positive or negative QRS trigger pulse is defined as follows:

Normally the trigger pulse is generated within 90 ms after the beginning of the QRS complex (the shape of the QRS complex determines the exact time).

QRS Trigger Duration

Key **7** sets the duration of the QRS trigger

select between: 50, 100, 150, and 200 ms

Printer Trace Alignment

For the ECG printout, two printer alignment settings can be selected.

Key **8** toggles between

baseline - traces are aligned to the baseline)

range - traces are aligned in such a way that the individual ECG signals do not overlap).

Printer trace alignment affects both the manual as well as the automatic printout. A change of the current setting is only valid on the printout after a new number of printer channels is selected by pressing the PRINTER CHANNEL key during or before printing, or after a new lead group is selected by pressing the lead keys LEAD ◁ LEAD ▷ during printing.

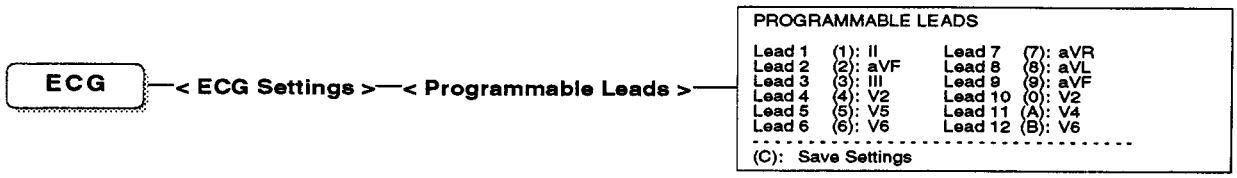
To save the settings made, press key **9.** Confirmation is given by the indication

* * * Settings memorized! * * *

ECG SETTINGS

Programmable Lead Sequence

In addition to the conventional lead order (Standard or Cabrera), you can define an individual lead sequence as follows:



The table shows the currently programmed leads. The numbers '1' to '0' and letters 'A' to 'B' select the positions for leads 1 through 12.

NOTE: *The rhythm leads R1, R2, R3 and r1 are selected directly in the rhythm mode (Chp. 3).*

The leads are changed with the keys NO − or YES + .

The following leads are available:

I	II	III	aVR	aVL	aVF	V1	V2	V3	V4
V5	V6	-aVR	DC1	DC2	D, A, J,	V7,	V8,	V9	

To display the new lead group (or change the lead group when printing in manual mode), press the lead key LEAD ◁ or LEAD ▷ until the new lead sequence appears.

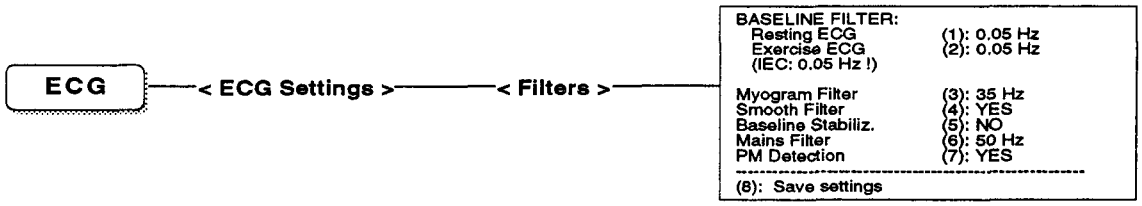
To save the settings made, press key **C**. Confirmation is given by the indication

*** Settings memorized! ***

ECG SETTINGS

Filter Settings & Pacemaker Detection

Before or at any time during the recording (resting or exercise ECG) a sophisticated set of filters can be selected to optimise the ECG waveform. The filter menu is reached as follows:



The following settings can be made:

Baseline filter

The value set is the lower limit of the frecency range and is normally set to 0.05Hz (IEC recommendation), i.e. a frequency range of 0.05 to 150Hz. The other settings should only be used when absolutely necessary as the possibility exists that they could affect the original ECG signal, especially the ST segments.

1 selects the **baseline filter for resting ECG** (select between 0.05, 0.12, 0.25 or 0.50 Hz). The selection is shown on the bottom line of both the automatic and the manual printout (e.g. **0.25** – 35 Hz)

2 selects **the baseline filter for exercise ECG** (select between 0.05, 0.12, 0.25 or 0.50 Hz). The selected setting is shown on the bottom line of the periodic printout (e.g. **0.05** – 35 Hz).

Myogram filter

The myogram filter reduces muscle induced noise. The use of the myogram filter reduces the signal amplitudes by 20%. Average cycles and measurements are not affected by this filter.

Select between 25 or 35 Hz. The selected filter setting is shown on the bottom line of the printout and is given on the screen (e.g. 0.05 - **35 Hz**).

The setting here defines the cutoff frequency. The filter is switched on of off with the FILTER key and described on the following page.

Smoothing filter

The smoothing filter (SSF - SCHILLER Smoothing Filter) suppresses high frequency artefacts between the QRS complexes.

The **smoothing filter** can be switched on and off (**only effective on automatic ECG printout**). When this filter is switched on, 'SSF' is shown on the bottom line of the automatic printout (resting and exercise ECG).

ECG SETTINGS

Baseline stabilizer

The baseline stabilizer (SBS SCHILLER Baseline Stabilizer) reduces baseline fluctuations without affecting the ECG signal. **Only effective on automatic ECG printout.**

The baseline stabilizer can be switched on and off (resting and exercise ECG).When this filter is switched on, 'SBS' is shown on the bottom line of the automatic printout (resting and exercise ECG).

Mains filter

The mains filter is an interference filter that suppresses AC interference without disordering the ECG. It should always be selected when recording an ECG.

Select between: OFF, 50 Hz (for most European countries), or 60 Hz (for the USA and other countries.
When the filter is set, 'Fxx' is shown on the printout (e.g. F50).

Pacemaker detection

When pacemaker detection is activated, markers will substitute pacemaker pulses both on the screen and on the printout.

Select between enable (YES) or disable (NO).

To save the settings made, press key **8**. Confirmation is given by the indication

* * * Settings memorized! * * *

Switching the Myogram Filter ON and OFF

By pressing the FILTER key, the myogram filter can be switched ON or OFF.

The status of the myogram filter is shown on the bottom left-hand side of the screen (baseline filter setting on the left, myogram filter setting on the right):

0.12 – **35 Hz** (Myogram filter **ON**)

0.12 – **150 Hz** (Myogram filter **OFF**)

Reset ECG Signal (Baseline Reset)

Temperature changes or electrical interferences may cause the traces to 'drift'. If this happens the baseline of the displayed ECG traces has to be reset.

By pressing the (baseline reset) key, the baseline of the displayed ECG traces are reset.

MACRO FUNCTION

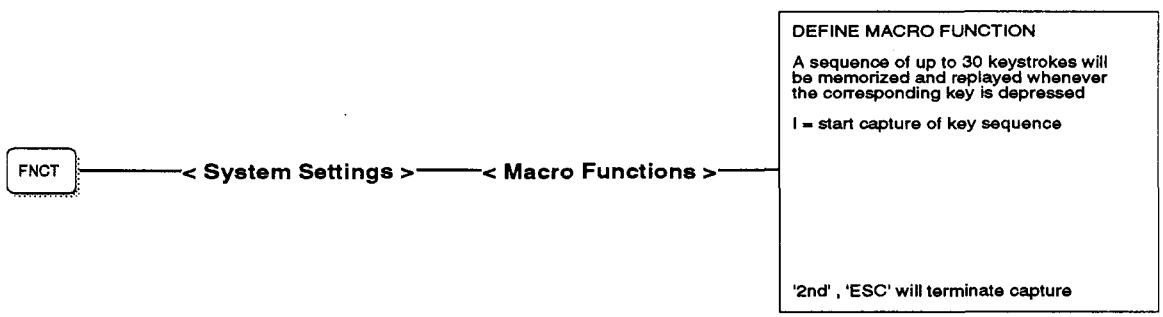
Any series of operation steps (or key strokes) can be programmed together in the form of a single **MACRO** function. This can be very useful to store often used procedures without having to re-enter all the data and parameters. It is worthwhile spending a few minutes to familiarise yourself with the Macro function - they can save you a lot of time and greatly simplify operation.

Macro functions can be assigned to the alphanumeric keys 1 to 6. Each single macro can be programmed to store up to 30 steps. All stored settings are recalled by just pressing [2ND] and then the selected key 1..6.

Before a macro is programmed, try out the steps first, note down the keystrokes and make sure they work. When a Macro has been programmed keep a record of all the steps and the result i.e. what the macro does, for future reference.

Store a Macro

Enter the main menu to program a macro as follows:



You are now in the Macro menu and you can commence to enter a series of steps that you wish to store.

- Start the recording by pressing key I (for input).
- Select a number key from **1** to **6** .

  This will be your macro number - 1 to 6. If a different key is pressed and an error message is displayed with an acoustic signal, try again. On the display the selected key appears as "**F1**" to "**F6**".
- Enter the series of keystrokes that you wish to be recalled when this macro is selected.

  a) In menus where a choice of selections exists, the selection must first be preset to a known value so that the unit knows the 'starting point'. To do this, whenever a multiple choice menu option is to be programmed (such as format selection), the slash key (/) must first be pressed to set the option to a known value (the first option).

  Press the [YES +] key until the desired setting option is displayed (see example).

MACRO FUNCTION

Store a Macro (Cont.)

b) If you want a specific lead group to be displayed and remembered as a macro function, activate the default setting first by pressing the keys [2ND] and [MONITOR CHANNEL].

The standard lead group I, II, III, aVR, aVL, aVF (6 monitor channels) will be displayed.

Use the lead keys [LEAD ◁] and [LEAD ▷] to select the desired lead group (full details are given in Chp. 3).

c) If you want a specific lead group to be printed out in manual mode and remembered as a macro function, activate the default setting first by pressing the keys [2ND] and [PRINTER CHANNEL].

The standard lead group I II III aVR aVL aVF (6 printer channels) will be displayed on bottom line of the screen.

Use the lead keys [LEAD ◁] and [LEAD ▷] to select the required lead group (full details are given in Chp. 3).

d) Do not forget to press the [FNCT] key to return to the normal screen presentation.

- Finish the recording by pressing the keys [2ND] followed by [ESC].

The saving of the macro is confirmed by an acoustic signal. The recording is stored until the function key is used again for a new macro.

Recall a Macro

NOTE: To recall a macro the screen must be 'clear'. That means, that no menu is allowed to be displayed.

- Press [2ND] and then the selected number key **1..6**.

MACRO FUNCTION

Macro Example

Suppose that for the exercise testing you wish to set the periodic printout format 1, ECG leads, to "SHORT 50 mm/s". You want Macro 1 to be used and assign it to number key **1**. To program this you would proceed as follows:

1. Enter the MACRO menu by pressing the keys [FNCT] **- 2 - 1.**
2. Press key **I** to start the recording.
3. Press number key **1** (this specifies that the following entries will be remembered as Macro 1).
4. Enter the key sequence [EXERCISE] -3-1-1 ("ECG leads" in the format menu 1 for the exercise testing).
5. Press the slash key (/) to reset the ECG leads to the standard setting - in this case NO.
6. Press key **1** (or [YES +]) until the required format "SHORT 50 mm/s" is displayed.
7. Press [FNCT] to exit the format menu.
8. To store the macro and exit the macro menu, press key [2ND] followed by [ESC].

The key sequence is now programmed to macro 1. Each time you recall macro 1 by pressing [2ND] followed by the number key **1**, the ECG lead format "SHORT 50 mm/s" will automatically be selected for the periodic printout of the exercise ECG.

Of course this is a very simple example, but you should be seeing the advantages of macros and how useful this function could be to store, for example commonly used ECG recording procedures.

CHAPTER 2

Electrode Attachments and Prerecording Preparations

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Comparison Table IEC-AHA 2.3
Resting ECG (With Standard 10-lead Cable) 2.4
Exercise ECG (With Standard 10-lead Cable) 2.5
Electrode Positions for Additional Leads 2.6
Electrode Positions for Nehb Leads 2.7
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Checking Electrode Resistance **2.9**
Check Skin/Electrode Resistance 2.9
Lead Off Indications **2.10**
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Individual Lead Sequence 2.11
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ELECTRODE PLACEMENT

General Information

The ECG signals are acquired by means of electrodes connected to the patient in the required configuration.

For the standard 12-lead ECG, nine active electrode signals are required.

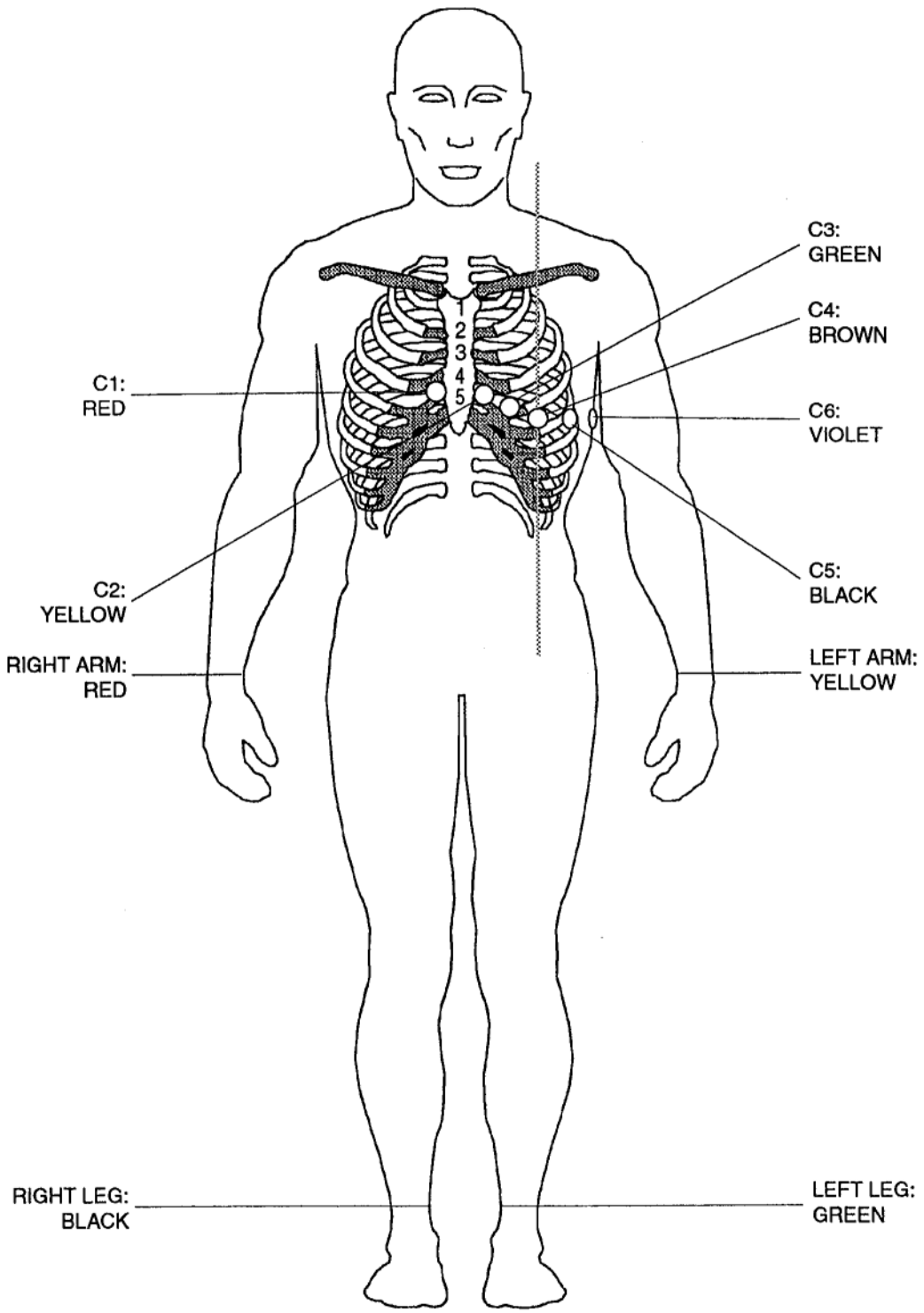
Comparison Table IEC-AHA

The following placements that are shown on the next pages are labelled with the colours according to IEC requirements. A table with the AHA format is given below:

IEC		AHA	
N	Black	RL	Green
R	Red	RA	White
C1	White/Red	V1	Brown/Red
C2	White/Yellow	V2	Brown/Yellow
C3	White/Green	V3	Brown/Green
C4	White/Brown	V4	Brown/Blue
C5	White/Black	V5	Brown/Orange
C6	White/Violet	V6	Brown/Violet
L	Yellow	LA	Black
F	Green	LL	Red

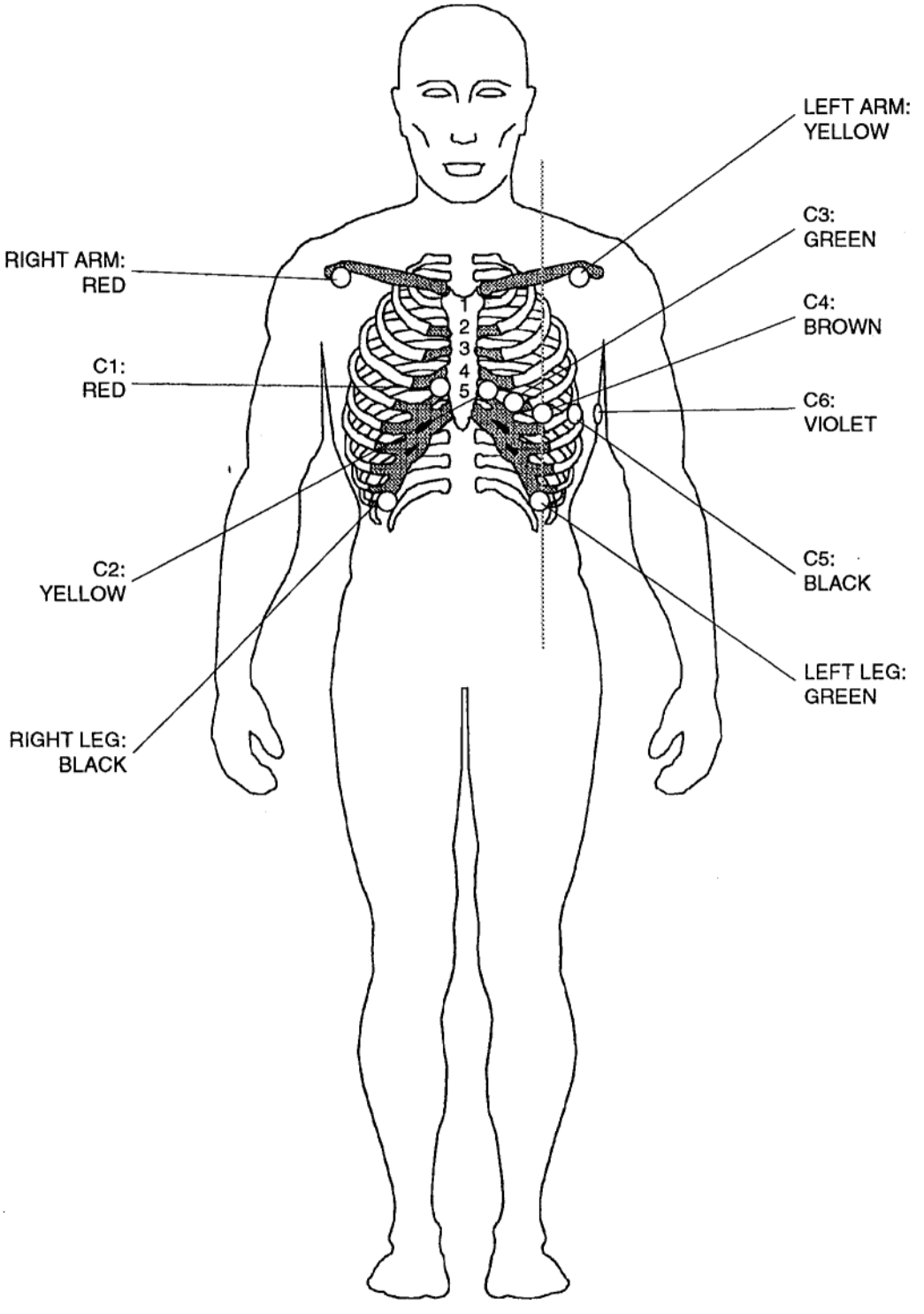
ELECTRODE PLACEMENT

Resting ECG (With Standard 10-lead Cable)



ELECTRODE PLACEMENT

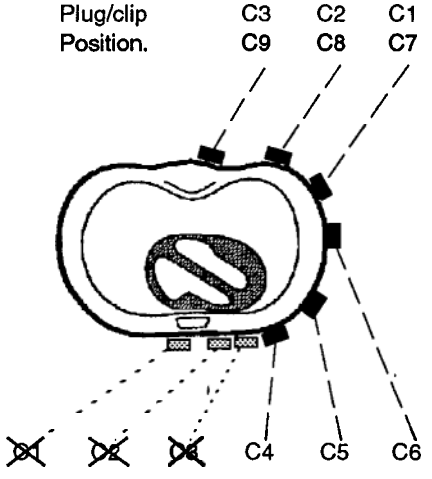
Exercise ECG (With Standard 10-lead Cable)



ELECTRODE PLACEMENT

Electrode Positions for Additional Leads

When using the **10-lead patient cable** the clips from the chest electrodes C1 through C3 have to be removed and connected to the electrodes C7 through C9 placed on the patients back in the appropriate positions.



IEC	AHA
Plug/clip C1 red to electrode C7	Plug V1 red to electrode V7
Plug/clip C2 yellow to electrode C8	Plug V2 yellow to electrode V8
Plug/clip C3 green to electrode C9	Plug V3 green to electrode V9

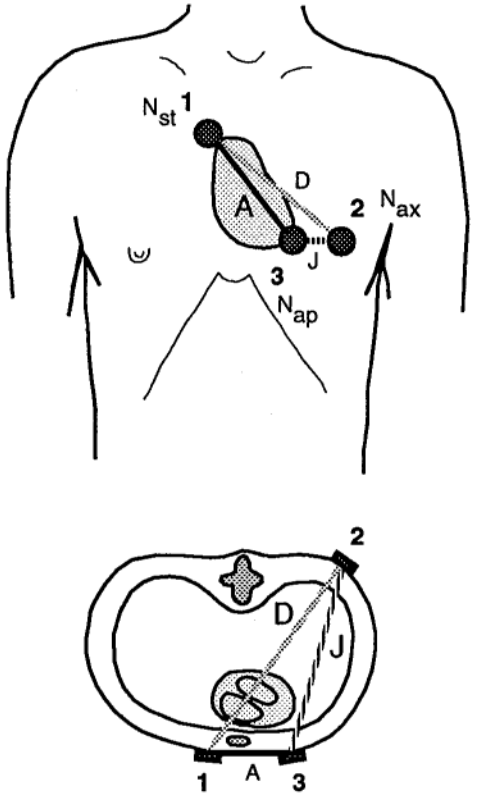
NOTE: The additional leads V7 through V9 can only be recorded in manual mode.

ELECTRODE PLACEMENT

Electrode Positions for Nehb Leads

To record the bipolar Nehb leads **D, A, J**, place electrodes as follows:

NOTE: *The Nehb leads can only be recorded in manual mode.*



10-lead Cable

IEC	Pos.	AHA
Plug R red to electrode on Nst (2nd rib at right sternal border)	1	Plug RA white to electrode Nst
Plug F green to electrode on Nap (anterior to the scapular apex)	2	Plug LL red to electrode on Nap
Plug L yellow to electrode on Nax (left posterior axillary line on a level with the scapular apex)	3	Plug LA black to electrode on Nax
Plug N to electrode on right leg		Plug RL green to electrode on right leg

ELECTRODE PLACEMENT

Applying the Electrodes to the Patient

The quality of the ECG is dependent on the preparation and the resistance between the skin and the electrode. To ensure a good quality ECG and minimise the skin/electrode resistance, remember the following points:

1. Ensure that the patient is warm and relaxed.
2. Shave electrode area before cleaning.
3. Thoroughly clean the area with alcohol.
4. When applying the electrodes ensure that a layer of gel is between the electrode and the skin.
5. Place the **C4** electrode first - in the fifth intercostal space on midclavicular line.
   Then place:
   - **C1** in fourth intercostal space at the right sternal border
   - **C2** in fourth intercostal space at the left sternal border
   - **C3** between, and equidistant to, C4 and C2
   - **C6** on left midaxillary line on the same level as C4
   - **C5** between, and equidistant to, C4 and C6

Following these simple guidelines will ensure good results every time.

Connect Patient Cable

Plug the patient cable into the cable socket (marked EKG/ECG) on the right-hand panel and secure with the two screws.

CAUTION!

ENSURE THAT DURING ECG RECORDING NEITHER THE PATIENT NOR THE CONDUCTING PARTS OF THE PATIENT CONNECTIONS AND ELECTRODES (INCLUDING THE NEUTRAL ELECTRODE) COME INTO CONTACT WITH OTHER PERSONS OR CONDUCTING OBJECTS (EVEN IF THESE ARE EARTHED).

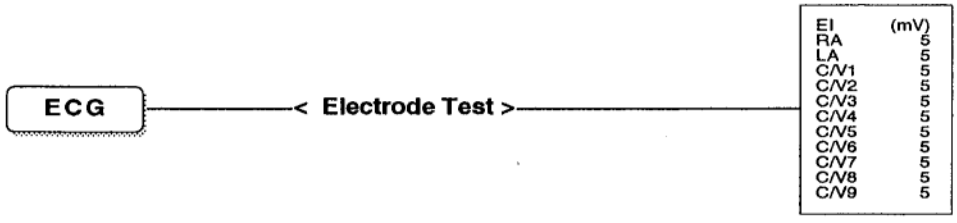
DEFIBRILLATION PROTECTED ONLY IF USED WITH ORIGINAL SCHILLER PATIENT CABLE!

CHECKING ELECTRODE RESISTANCE

Check Skin/Electrode Resistance

After the electrodes have been applied to the patient and the patient cable plugged in, use the electrode test option of the AT-10 to ensure that the electrodes are making good contact with the skin.

Check the skin resistance as follows:



The right-hand column gives the detected voltage for each electrode in millivolts. This value represents the voltage measured between the electrode on the left leg and each of the individual electrodes. To ensure impeccable ECG recording, the value of each electrode should be within the range of ±50 mV.

What to do when an electrode is making poor contact

- If the value of an electrode exceeds or falls below the limit of ±50 mV, remove the questionable electrode and clean it.
- Clean the skin area, apply some gel to the electrode and reapply it to the patient.

LEAD OFF INDICATIONS

On the Screen

If a lead-off status or poor electrode contact is detected at any time on any of the electrode connections, an audible alarm is given and the lead that is high resistance flashes in the lead status field in the upper right corner of the screen. Note that the indication in this field shows the standard lead designation. If the patient cable is not correctly plugged in or if the connection to lead F is interrupted, the entire lead status field will flash. When any of this happens, check the electrode connections (see also the previous paragraph "Check Skin/Electrode Resistance").

In exceptional circumstances, the indicator continues to flash after the electrode has been reapplied. This can indicate a problem with the patient cable. Use the cable tester (see Chap. 7, "Checking the Patient Cable) to check the cable.

On the Printout (manual printing)

If an electrode signal cannot be picked up, a lead-off message will appear on the bottom line of the manual printout. "C4 off", for instance, indicates a problem with electrode C4 which may make poor or no contact or is disconnected from the recording unit.

LEAD SEQUENCE

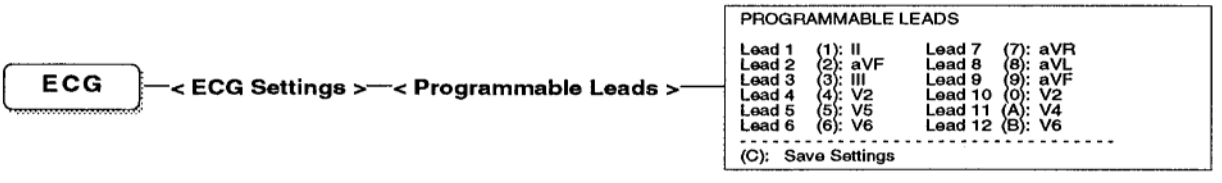
Standard / Cabrera Lead Sequence

Check the selected lead sequence as follows:

If necessary, change the lead sequence with key 2.

Individual Lead Sequence

If an individually defined lead sequence should be checked, proceed as follows:

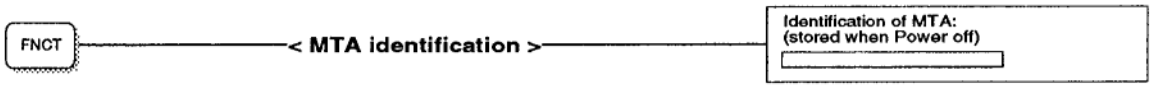


If necessary, correct the lead with the appropriate key.

MTA IDENTIFICATION

This function is to register the name of the medical assistant carrying out the recording and must be entered every time the unit is used. The MTA is identified on each automatic printout.

Press the following keys to reach the menu:

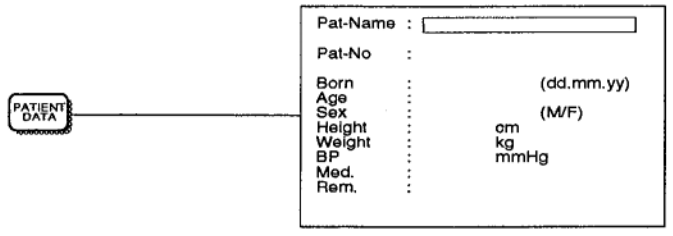


Enter the name with the keypad (the maximum number of characters is 23).

When complete exit the menu with FNCT or ESC.

PATIENT DATA

Each ECG is printed with the patient name and other patient details (in manual mode, only patient name and number are given on the printout). The patient data must be entered before starting an ECG recording. To enter the patient data menu proceed as follows:



NOTE: *If a new patient name is entered, all the other patient data is automatically deleted (this also applies to spirometry values for this patient). All patient data is deleted when the unit is switched off.*

Pat. Name: Patient name

Pat. No.: Patient number

Born*: The date of birth has to be entered in the order dd.mm.yy or mm-dd-yy (separated with a full stop [.], hyphen [-] or slash [/]).
Example: 25.05.66 or 05-25-66

Age: The age is calculated automatically by the unit on the basis of the entered date of birth.
up to 2 years: Number of months
up to 6 years: Number of years and months
over 6 years: Number of years

Sex: M (male) or F (female)

Height*: in cm or inch

Weight*: in kg or lb

BP: Blood pressure in mmHg systolic/diastolic:
sss/ddd or *sss.ddd*

Med.*: Medication

Rem.*: Remarks

- Confirm each entry with **ENTER**.
- Use the direction keys to move the cursor to the entry line.
- To exit the menu, press FNCT or ESC

NOTE: ** Options are set in the unit configuration menu (FNCT -2-4)*

CHAPTER 3

Recording of Resting ECGs

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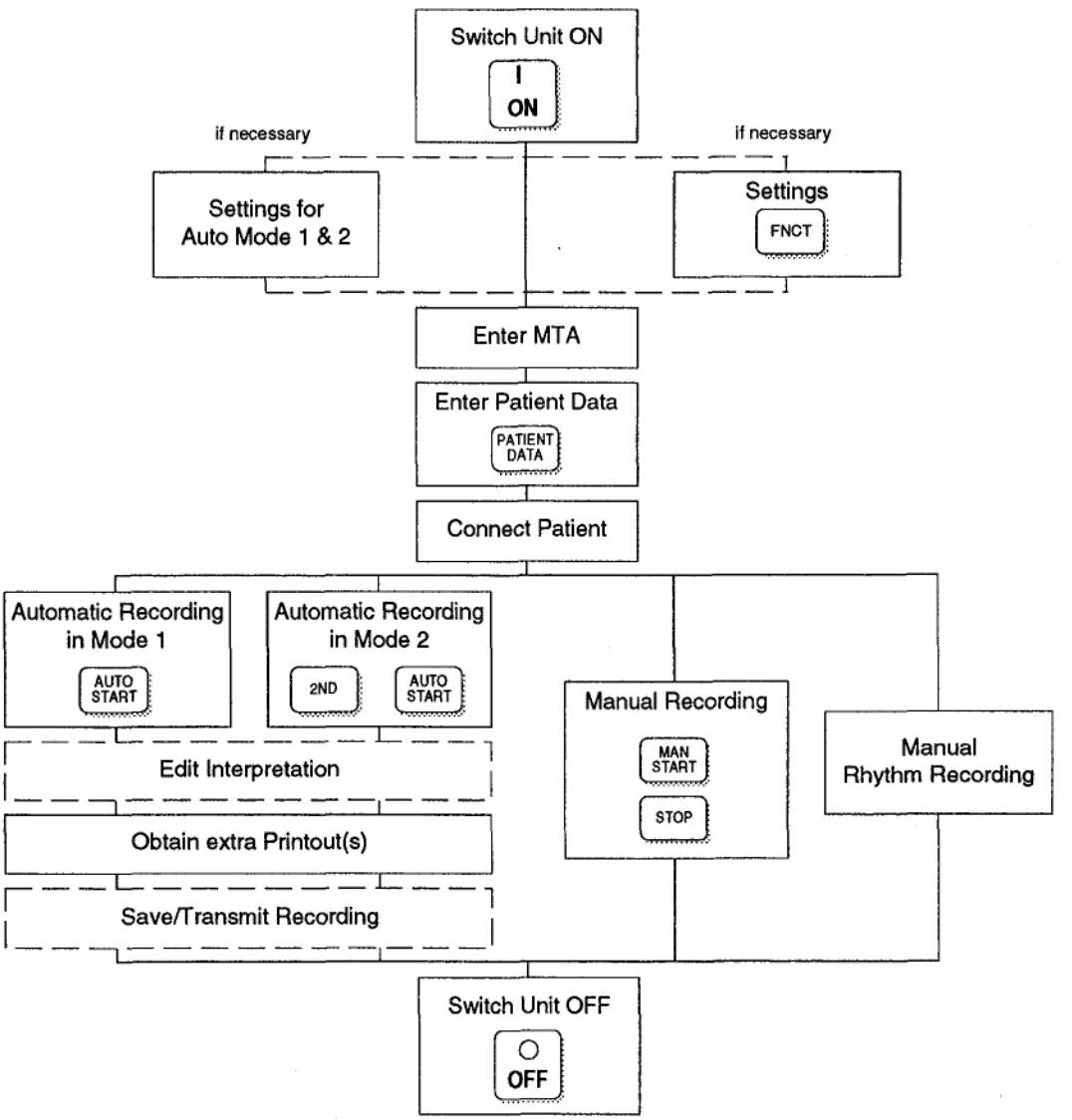
OVERVIEW ECG RECORDING



GENERAL INFORMATION

ECG signals are recorded in real-time and the most recent 10 seconds are kept in memory and are constantly updated.

Resting ECG Recording

There are various methods of recording resting ECGs with the AT-10. When the cardiograph is switched on and the electrodes are connected to the patient it begins acquiring the incoming ECG signals for either on-screen monitoring or paper registration.

ECG Signal Monitoring

- Selection of monitor speed and sensitivity
- Selection of lead sequence and lead group
- Selection of channel mode
- Freeze/release display
- Print out screen as displayed
- Save display settings

Automatic Recording and Printing

The most recent 10 seconds of ECG data are used for processing, averaging and printing.

- Two automatic mode formats (1 + 2)
- Several print options for ECG leads and average QRS
- Reference marks for average QRS
- Printout with ECG measurements
- Possibility to adjust ECG interpretation
- Printout with ECG interpretation
- Prevent printing/define number of copies
- Obtain extra printouts in different formats
- Display average cycles and interpretation statements on the screen

Manual Recording and Printing

- Selection of printing speed and sensitivity
- Selection of lead sequence and lead group
- User-defined number of printer channels
- Channel selection for printout
- Footswitch operation to start/stop manual printing

Resting ECG Recording (Cont.)

Rhythm Recording and Printing

- Format selection
- Normal or low amplitude
- Monitoring of up to 2 rhythm leads

Specific ECG Options

With the appropriate software options installed in the unit, the AT-10 can expand its diagnostic potential.

For ECG applications the following options are available :

- Measurement
- Interpretation
- Pacemaker Measurement
- Late Potential Analysis
- Heart Rate Variability

ECG SIGNAL MONITORING

Select Number of Display Channels

On the screen either 3, 6 or 8 leads can be displayed (when the unit is switched on, it always remembers the last display configuration selected before switching off).

- By pressing the key MONITOR CHANNEL the display toggles between **3, 6 or 8 channels.**

- In **3 or 6-channel mode** all configured leads (Standard or Cabrera leads followed by the user-defined leads) can be selected group by group by pressing the lead keys LEAD ◁ or LEAD ▷.

  - In 3-channel mode, the following lead groups can be displayed:

THREE LEAD GROUPS								
I	aVR	V1	V4	programmed lead 1	programmed lead 4	programmed lead 7	programmed lead 10	0
II	aVL	V2	V5	programmed lead 2	programmed lead 5	programmed lead 8	programmed lead 11	0
III	aVF	V3	V6	programmed lead 3	programmed lead 6	programmed lead 9	programmed lead 12	0

  - In 6-channel mode, the following lead groups can be displayed:

6 LEAD GROUPS				
I	V1	programmed lead 1	programmed lead 7	0
II	V2	programmed lead 2	programmed lead 8	0
III	V3	programmed lead 3	programmed lead 9	0
aVR	V4	programmed lead 4	programmed lead 10	0
aVL	V5	programmed lead 5	programmed lead 11	0
aVF	V6	programmed lead 6	programmed lead 12	0

NOTE: *Lead groups can be changed at any time during recording.*

- In **8-channel mode** the lead grouping is fixed (no changes possible).

ECG SIGNAL MONITORING

Select ECG Signal Level/Select ECG Display Speed

- By pressing the MONITOR mm/mV key, signal amplification is switched between the following values:
  - 5 or 10 mm/mV with 3 leads,
  - 2.5 or 5 mm/mV with more than 3 leads

The amplitude of the 1 mV pulse displayed to the left of the first lead gives the selected sensitivity.

- By pressing key MONITOR mm/s the display speed is switched between 12.5, 25 and 62.5 mm/s.

The time reference is given on the bottom of the screen indicated by '1s' and a series of points; the time difference from point to point is 1 sec.

The above values represent the ECG size and speed on the printout initiated with the PRINT SCREEN key (see below).

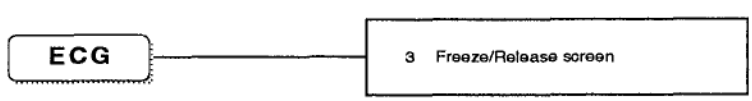
Inserting a Calibration Signal

- By pressing the key 1 mV a square wave 1 mV calibration signal can be manually inserted into the recorded signals.

The amplitude of the square wave pulse depends on the sensitivity selected with the MONITOR mm/mV key.

Freeze/Release Display

The ECG signals displayed on the screen can be "frozen" at any time for closer examination as follows:



The recording of the ECG continues while the screen is frozen.

Print Screen

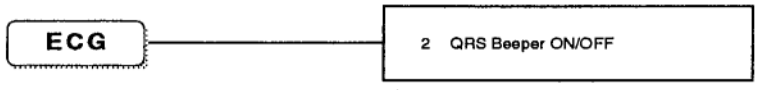
With the PRINT SCREEN key, the screen can be printed as displayed.

ECG SIGNAL MONITORING

Switch Acoustic QRS Signal ON or OFF

An acoustic indication of the heart rate can be provided by means of the QRS beeper.

This signal is turned on or off as follows:



AUTOMATIC FORMAT SETTINGS

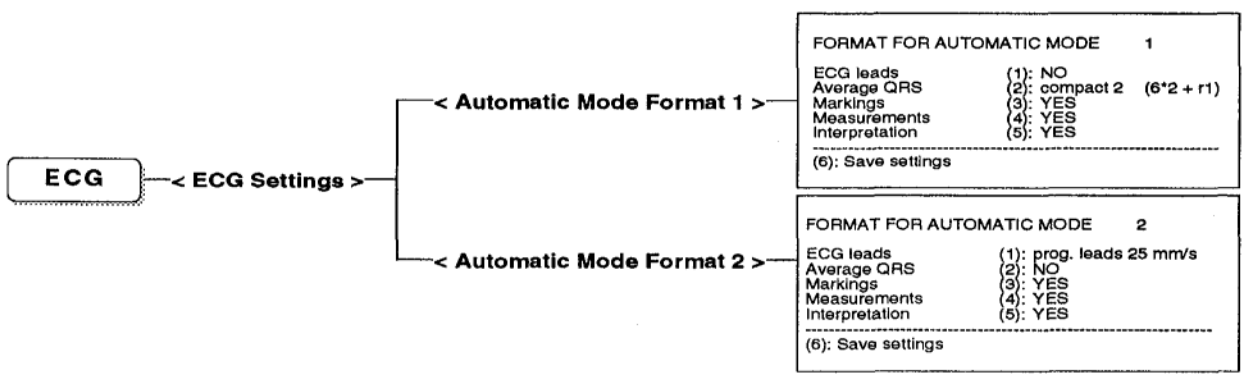
General Information

NOTE: *Certain information about functions that are described in the following paragraphs, is only relevant if the appropriate software options are installed.*

There are several settings which can be made for automatic mode recording which determine the format and content of the printout. Two automatic mode formats can be programmed (auto format 1 and 2). The key AUTO START commences an auto mode recording in format 1. Pressing the 2nd key with the AUTO start key commences a resting ECG in the second format.

Define Auto Mode Format 1 + 2

To reach the menu and define the settings for the automatic mode format 1 or 2, proceed as follows:



AUTOMATIC FORMAT SETTINGS

In both configurations (Automatic Mode Format 1 and 2) the following selections can be made:

ECG Leads

The configuration of the printed leads is determined by pressing key '**1**' as follows:

NO No leads are printed.

*3*4 leads + 1 rhy. (r1)* 12 leads (4 columns with 3 ECGs each) and one rhythm strip (user programmed lead r1) are printed.

*3*4 leads + 3 rhy. (R1-R3)* 12 leads (4 columns with 3 ECGs each) and three rhythm strips (user programmed leads R1, R2 and R3) are printed.

SHORT: 25 mm/s 12 leads are printed in "short" format; i.e. over 1 page , at a chart speed of 25 mm/s.

SHORT: 50 mm/s As before, but chart speed 50 mm/s.

SHORT: 100 mm/s As before, but chart speed 100 mm/s.

LONG: 25 mm/s 12 leads* are printed in "long" format; i.e. over 2 pages, at a chart speed of 25 mm/s.

LONG: 50 mm/s As before, but chart speed 50 mm/s.

LONG: 100 mm/s As before, but chart speed 100 mm/s.

When SHORT or LONG formats are selected, pressing PRINTER CHANNEL *alters the layout of the print-out:*

3 channels => 4 columns of 3 ECG leads
6 channels => 2 columns of 6 ECG leads

LONG formats print twice as many heart beats as the SHORT format.

Progr. leads print as many channels as configured by pressing the key "PRINTER CHANNEL"

prog. leads 25 mm/s Individually user defined leads printed at a chart speed of 25 mm/s.

prog. leads 50 mm/s As before, but chart speed 50 mm/s.

prog. leads 100 mm/s As before, but chart speed 100 mm/s.

prog. leads (25 mm/s, 5 s) The last 5 seconds of user defined leads with a chart speed of 25 mm/s.

AUTOMATIC FORMAT SETTINGS

Average QRS

Only available if either Interpretation (C) or Measurement (M) option is installed.

The configuration of the printed leads is determined by pressing key '**2**' as follows:

NO No average cycles are printed.

*Compact 1 (3*4 + R1,R2,R3)* The average QRS cycles of the 12 leads (4 columns with 3 ECGs each) and three rhythm leads are printed on one page at a chart speed of 25 mm/s.

*Compact 2 (6*2 + r1)* The average QRS cycles of the 12 leads (2 columns with 6 ECGs each) and 1 rhythm lead (user programmed lead r1) are printed on one page.

*2*6 leads + 3*rhy. (R1-R3)* The average QRS cycles of the 12 leads (6 columns with 2 ECGs each) and three rhythm leads are printed.

*3*4 leads + 1*rhy. (r1)* The average QRS cycles of the 12 leads (4 columns with 3 ECGs each on two pages) and 1 rhythm lead (user programmed lead R1) are printed.

Markings

(for Average QRS) - *Only available if either Interpretation (i) or Measurement (M) option is installed.*

Pressing key '**3**' provides vertical reference marks at the beginning and end of the P wave and QRS complexes and at the end of the T wave. These marks can be added (YES) or omitted (NO).

Measurements

Only available if either Interpretation (i) or Measurement (M) option is installed.

The ECG measurements contains a printed table of the amplitude value and the time length for each of the 12 leads.

Pressing key '**4**' provides a measurement table of all important parameters at the end of the printout. The table can be included (YES) or omitted (NO).

Full details of the Measurement option are given in the SCHILLER ECG Measurement and Interpretation Booklet (art. no. 2.510 179).

AUTOMATIC FORMAT SETTINGS

Interpretation Statements *Only available if Interpretation (i) option is installed.*

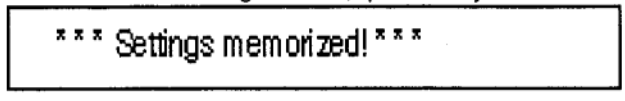
The ECG interpretation contains diagnostic references that can be printed and appear on the display.

Pressing key **'5'** provides an interpretation of the recorded ECG. The interpretation statements can be included (YES) or omitted (NO).

Full details of the Interpretation option are given in the SCHILLER ECG Measurement and Interpretation Booklet (art. no. 2.510 179).

Other settings can be made for the interpretation statements (see following page).

To save the settings made, press key **6**. Confirmation is given by the indication



AUTOMATIC FORMAT SETTINGS

Interpretation Settings

NOTE: *Only available if Interpretation (i) option is installed.*

Write — The statements "UNCONFIRMED REPORT" and "ABNORMAL ECG" may be distressing to the patient. These statements can be omitted. Set to YES or NO with the keys **1** and **2**.

Sensitivity — Certain nonspecific ECG diagnosis can be suppressed. This may be advisable when carrying out ECGs for screening. For detailed patient analysis it is suggested that this is set as normal.

Set to NORMAL or LOW with the key **3**.

To save the settings made, press key **4**. Confirmation is given by the indication

*** Settings memorized! ***

Display Average ECG Complexes

NOTE: *Only available if Measurement (M) or Interpretation (i) option is installed.*

Result Display — When this function is enabled (press key **4** and set to YES) , the average cycles will automatically be displayed when the AUTO START key is pressed and the recorded ECG data has been evaluated.

The results will be displayed regardless of whether average QRS cycles have been selected for the printout.

AUTOMATIC ECG RECORDING

Automatic ECG Recording

To carry out an auto mode ECG proceed as follows:

- Switch the unit on and define the Automatic Mode format 1 and 2 as detailed in the previous paragraphs, if not already done.
- Connect the patient cable as detailed in Chp. 2.
- Enter patient data as detailed in Chp. 2.

Format 1

- To start the recording in Auto Format 1, press [AUTO START].

Format 2

- To start the recording in Auto Format 2, press [2ND] followed by [AUTO START].

The message "ACQUIRING DATA" is briefly displayed in the information box on the display. This is followed by the message "PROCESSING ..." A printout with the ECG is given after a few seconds in the format defined.

The ECG data remains in the memory until it is overwritten by another recording or the unit is switched off. The interpretation statements can be edited and further printouts obtained in varying formats all the time the ECG is stored. This is described in the following paragraphs.

Changing the Format / Obtaining Extra Printouts

Format 1

- To obtain another printout of the last recorded and evaluated data in Format 1, press [COPY].

When an ECG has been taken in auto mode, the format can be changed (and printout obtained) as many times as you like. Simply enter the Automatic mode format and select "ECG Settings". Change whatever parameters you wish. Pressing '**COPY**' gives the printout of the stored ECG in the changed format.

The sensitivity of the printout can be changed at any time using the mm/mV keys '**8**' to '**-**'.

Format 2

- To obtain another printout of the last recorded and evaluated data in Format 2, press [2ND] followed by [COPY].

AUTOMATIC ECG RECORDING

Edit Interpretation Report

NOTE: *Only available if Interpretation (C) option is installed.*

ECG ——< Edit Interpretation >

Following keys are used for editing:

- ◁ ▷ moves the cursor to the right or to the left.
- △ ▽ moves the cursor up or down
- **DELETE** deletes a wrongly typed character
- 2ND + ◁ moves the cursor to the beginning of the line
- 2ND + ▷ moves the cursor to the end of the line
- 2ND **+ W** deletes the word where the cursor is positioned (CAPS key must be activated).
- 2ND **+ DELETE** deletes the line where the cursor is positioned
- **ENTER** Line break at cursor position. Moves the text entry point to the beginning of the next line.

NOTE: *When changing the interpretation statements, each text line will start with a point when a new printout is obtained.*

Display Average QRS Cycles or Interpretation Statements

NOTE: *Only available if Interpretation (C) option or Measurement option (M) is installed.*

When an ECG is stored pressing CHANGE SCREEN toggles the screen information as follows:

- Average QRS
- Interpretation Statement
- ECG traces of current recording

Screen presentation of average cycles and interpretation statements is the same as in the automatic printout (ECG -5-1-2/5).

MANUAL ECG RECORDING

ECG acquisition commences as soon as the patient is connected and the ECG trace is displayed on the LCD. The lead display and recording parameters can be changed at any time as detailed in Chapter 1. A printout of the ECG can be obtained at any time.

Printing in Manual Mode

Two methods are available:

1) Press [PRINT SCREEN] to obtain a printout of the screen content.

2) Press [MAN START] to obtain a continuous printout.

- The printout is continuous until the key [STOP] is pressed.

Selecting Number of Channels for Manual Printing

The number of channels that can be printed are 3, 6 or a user defined number. Set the user defined number of channels as follows:

Press key '**3**' to set the programmable channels (4, 5 or 7).

Before or during the printout the number of channels printed is changed by pressing [PRINTER CHANNEL].

During the printout the lead sequence can be changed with the [LEAD ◁] or [LEAD ▷] key. The printed leads are the standard leads followed by the user programmed leads. For example when 3 channels are selected with the [PRINTER CHANNEL] key, the [LEAD ▷] key must be pressed 4 times to print all 12 leads (i.e. 4 prints each with three leads).

The leads that will be, or are being printed are displayed on the bottom, right-hand side of the screen.

NOTE: *When less than 6 channels are selected (i.e. the number of user-definable channels is set to 4 or 5) , only the first leads of a lead group are printed. When 7 channels are selected, the 6-lead group and the first lead of the following group is printed.*

MANUAL ECG RECORDING

Select Printing Speed and Print Size

The printer speed is adjusted with the dual purpose keys '**1**' to '**7**' on the alphanumeric keyboard giving values of 2.5, 5, 10, 12.5, 25, 50 or 100 mm/s.

The size of the printout (i.e. the height of the QRS complexes) is adjusted with the dual purpose keys '**8**' to '**-**' on the alphanumeric keyboard giving values of 2.5, 5, 10, or 20 mm/mV

The selected values are displayed on the lower part of the monitor and printout.

NOTE: *The number of channels, speed and sensitivity can only be changed when there are no open menus or setup choices.*

Printing speed and size can be changed at any time before or during the printout.

Start/Stop Printing with Footswitch

A footswitch can be used with the AT-10 to start or stop an ECG printout in manual mode.

For footswitch operation, proceed as follows:

- Plug the footswitch cable into the DATA I/O socket at the rear of the unit.
- Select the footswitch mode and switch the footswitch on (with key '**1**' in the menu).

- Press the key MAN START and then the STOP key.

  When the STOP key is pressed again, the paper is moved to the start position.

  - Press the footswitch **to start** the printout.
  - Release the footswitch **to stop** the printout.

CAUTION!

THE FOOTSWITCH IS NOT INTENDED FOR USE IN A WET OR MOIST ENVIRONMENT!

RHYTHM RECORDING

Rhythm recording is the name given to "long-term" ECG monitoring. The rhythm monitoring of ECG signals allows the constant recording of one or two specified leads for an unlimited length of time (limited only by the amount of paper).

To enter the rhythm menu and define the format, proceed as follows:

- Press key **1** to select the required **rhythm lead R1**.
- Press key **2** to select the required **rhythm lead R2**.
- Press key **3** to select the required **rhythm lead R3.**
- Press key **4** to select the required **rhythm lead r1**.

NOTE: *Rhythm lead definitions apply to the following settings:*

- ECG *-1-1-5 +* ECG *-5-1/2-1/2*
- EXERCISE *- 3-3-6+* EXERCISE *-3-1/2-1/2*
- MEMORY *-2-1-5/6 +* MEMORY *- 2-2-7*

- Press key **5** to select the **printout format**:
  - R1 90 sec/page (printout every 90 seconds)
  - R1 5 min/page (printout every 5 minutes)
  - R1 10 min/page (printout every 10 minutes)

- Press key **6** to select the sensitivity **(amplitude)**:
  - NORMAL
  - LOW (half amplitude)
- Key **7** prints a page before enough data has been recorded for the printout at the preset interval.
- Key **8** prints the last page again.
- Key **9** starts the rhythm recording. The printout is started after enough data for one page is available, i.e. after 90 seconds, 5, or 10 minutes depending on the selected format.
- Key **0** stops the rhythm recording and immediately starts a printout with the data that is currently available.
- Key **A** saves the settings made (format and amplitude). These settings will be retained and will be available next time the rhythm mode is selected.

CHAPTER 4

Recording of Exercise ECGs

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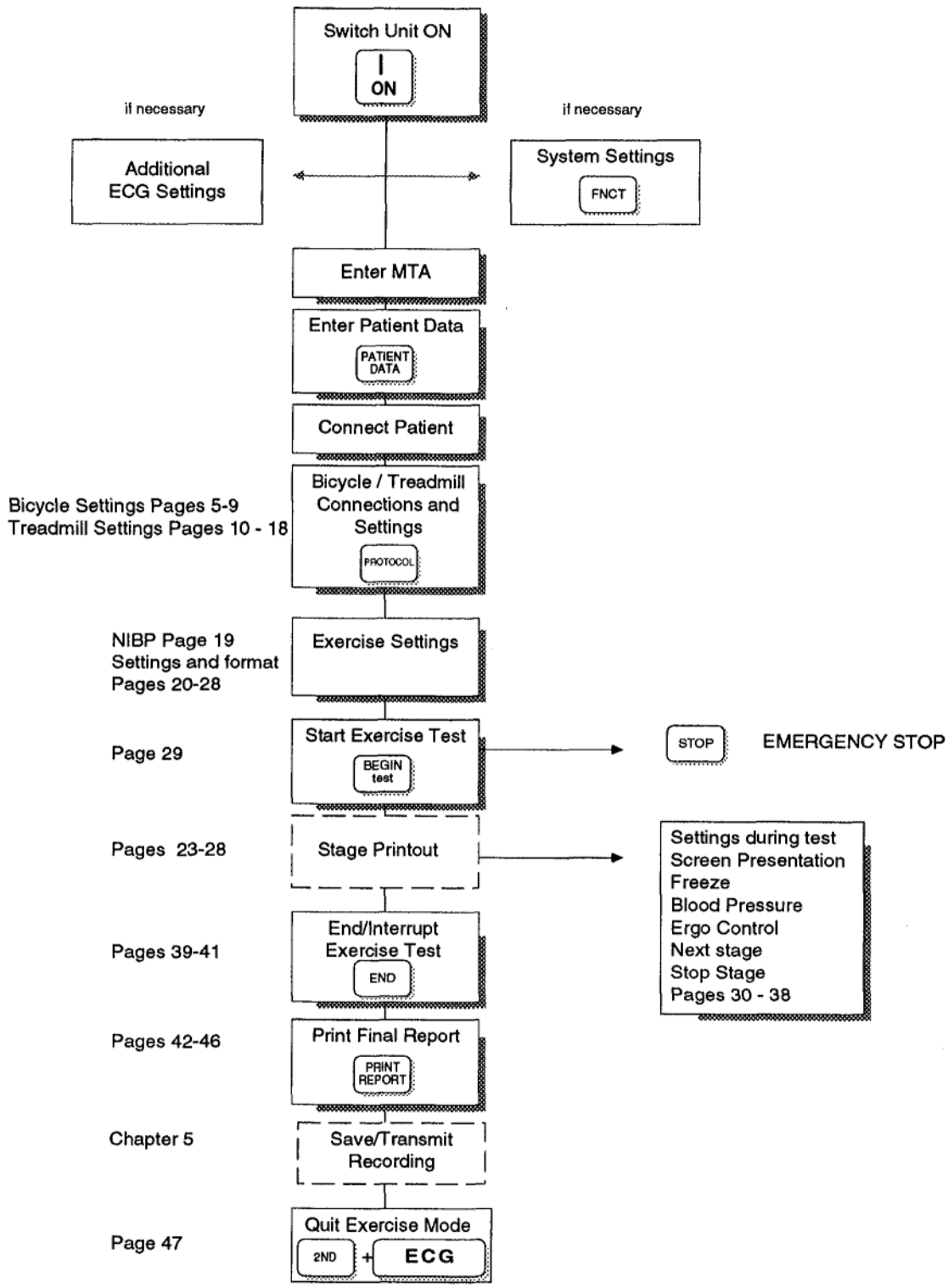
EXERCISE TEST OVERVIEW



GENERAL INFORMATION

For the recording of exercise ECGs the AT-10 can be used in conjunction with either a bicycle ergometer or a treadmill with remote control. Once programmed, the exercise test procedure is automatically controlled from the AT-10.

Features of the Exercise Test Program

Ergometer

- 4 user-programmable test protocols for bicycle ergometer
- Ramp protocol for bicycle (can be selected for each of the four user protocols)
- Conconi test protocol for treadmill and bicycle
- 5 standard and 5 user-programmable protocols for treadmill
- 1 ramp protocol for treadmill
- Treadmill speed selection for pre-exercise and recovery phase

Blood Pressure Measurements

- Blood pressure measurements at preset intervals during exercise and recovery phase
- Blood pressure measurements at any time during interval operation
- Manual entry of blood pressure values

Periodic Printout

- Format selection (ECG leads, average complexes, measurement values) and setting of writing intervals
- Second programmable format to obtain extra printouts at any time during the exercise phase
- User-defined ST measurement point

Criteria for Interruption

- Interruption of exercise phase at any time
- Default criteria
- Editing of criteria to suit user-specific needs
- Criteria selection to indicate cause for interruption in final report

Final Report

- Comprehensive final report at the end of the exercise test
- User-defined rhythm lead in final report

BICYCLE SETTINGS

Preparations

- On the AT-10, ensure that the mains filter is activated.
- Ensure that the recording unit and the bicycle are connected to the same common ground.
- Ensure that the potential equalization stud is connected to common ground.

Connect Bicycle

The bicycle must be connected to the relevant socket(s) of the AT-10 (see Chp. 1, "External Connections").

- A standard **bicycle ergometer (analogue) type**, the 5-pin plug is connected to the "Ergo" interface socket at the rear of the unit.
- For **ergometers with integral blood pressure measurement**, the 5-pin plug is connected to the "Ergo" interface, and the data line is connected to the RS-232 port 1.
- For the **ergometer ERGOLINE 900** or **SCHILLER ERG 1**, cable set no. 2.310063 must be used (available upon request by SCHILLER).
- **Digitally controlled bicycle ergometers** are connected to the RS-232 port 2.

Connect the ergometer to the mains supply.

Select Bicycle

The bicycle must be selected in the exercise settings menu as follows:

- Key **1** selects the type of bicycle or treadmill to be used.

  The choices available for selection are:

  - **Bicycle 1V/100W** This is the normal setting to be selected when working with all voltage-controlled bicycle ergometers (1 V corresponds to 100 W).

NOTE: ***Before** using the ergometer ERGOLINE 900 or SCHILLER ERG 1, select "EBM 502/3" in the blood pressure menu.*

  - **Bicycle RS232** Select this setting when using a Dynavit M900 bicycle ergometer with serial interface (for Dynavit M900 with analog control select the setting "Bicycle 1V/100W").

- Key **2** saves the settings made.

BICYCLE SETTINGS

Select Protocol for Bicycle Test

Following protocols can be selected for the bicycle test:

- four user-defined protocols
- Ramp protocol (for each of the four user protocols)
- Conconi protocol

The protocol identified as active protocol (number 1 in the example above) will be applied for the bicycle test.

User-defined protocols

- Press keys **1, 2, 3,** and **4** to display the user-defined protocols 1 to 4 and change any settings.

The protocol selected will be the new "active protocol". The following example shows a user-defined protocol:

Protocol:	number	1
Base load:	50	W
Load step:	25	W
Step interval:	2	min
Writing Interval:	2	min
Recovery load:	25	W
G = save setting		

- Enter the desired values with the numeric keys and confirm each entry with **ENTER** or with the direction key ▽. If it is only required to alter specific entries in the protocol, the cursor can be moved to the required position by means of the direction keys or the **ENTER** key.
- The complete protocol can be stored by pressing key **G**. The protocol will then be retained and will be available the next time the exercise testing mode is entered and one of the bicycle settings selected.

  The values entered for **load step** and **step interval** determine the increases in workload during the test. In the above example the base load is 50 W. From the first stage on, the load is increased continuously by 25 W every 2 minutes. So for example, after 4 minutes the work load is 100 W and after 6 minutes, the load is 125 W.

Base load This is the load which is applied at the beginning of the test .

Load step The 'load step' determines the load increase for each step.

NOTES: *Depending on the type of ergometer, the exercise test will continue to apply load steps (unless manually interrupted) up to a maximum load of 900 W.*

Although 900 W may be indicated on the unit, the actual load may be less, dependent on the load capacity of the bicycle.

BICYCLE SETTINGS

Step Interval

The 'step interval' determines the length of time a load step is maintained before moving on to the next one.

Writing Interval

The 'writing interval' indicates the intervals at which the ECG recording in the defined format is printed out during the exercise phase. If no period printout is required, type in a zero (0). If a printout at the end of each stage is required set to 9.

Recovery load

The 'recovery load' is the load which will be imposed during the recovery phase to which the ergometer returns as soon as the exercise test is interrupted. At the end of the recovery phase, the load is returned to 10 Watts.

To define the resting load, you can either enter the load you require or program the unit to automatically impose a predetermined load by entering "99".

In the latter case, the resting load is dependent upon the maximum working load as follows:

Max. working load	**resting load**
>150 W	50 W
150 W	<25 W

BICYCLE SETTINGS

RAMP Protocol

The RAMP protocol option for a bicycle test allows you to apply continuous load increases, i.e. the work load will increase gradually during a step and not instantly.

- Select the required user-defined protocol with keys **1, 2, 3** or **4.**
- Press key **R.** This will activate the RAMP protocol marked by the annotation (RAMP) next to the protocol number.

NOTE: *The ramp option can be selected for all bicycle protocols . To deactivate the ramp option, press key R again.*

The following shows a ramp protocol example:

Protocol:	number 1 (RAMP)	
Base load:	50	W
Load step:	25	W
Step interval:	2	min
Writing Interval:	2	min
Recovery load:	25	W
G = save setting		

- Enter the desired values with the numeric keys and confirm each entry with **ENTER** or with the direction key ▽ . If it is only required to alter specific entries in the protocol, the cursor can be moved to the required position by means of the direction keys or the **ENTER** key.
- In the above example a base load of 50W will be applied at the start of the test . This load will be constantly increased by 25W during the first step of 2 minutes. With the beginning of each new load step it will continue to increase constantly by 25W.
- The complete protocol can be stored by pressing the key **G.** The protocol will be retained and will be available the next time you enter the exercise testing mode with one of the bicycle settings selected.

BICYCLE SETTINGS

Conconi Protocol

- Key **5** displays the protocol for the CONCONI test. The following shows a typical protocol example:

Bicycle CONCONI-Test

Start load	(1):	50 W
Duration 1. stage	(2):	120 s
Load Augmentation	(3):	10 W
Report at stg. end	(4):	ON
Recovery load	(5):	40 W

(6): Save settings

Work per stage : 6.000 kJ

Stage	Time from beginning	Duration of stage	Load
1:	0 s	120 s	50 W
2:	120 s	100 s	60 W
3:	220 s	86 s	70 W
4:	306 s	75 s	80 W
5:	381 s	67 s	90 W
6:	448 s	60 s	100 W
7:	508 s	55 s	110 W
8:	563 s	50 s	120 W
9:	613 s	46 s	130 W
10:	659 s	43 s	140 W
11:	702 s	40 s	150 W
12:	742 s	38 s	160 W

- The Conconi test is based on a constant work output in Joules (or kJ) over each stage. When the load of the bicycle is increased, the stage time is decreased in the same relation so that the work output coefficient remains constant (as calculated on the first stage).
  - Enter the start load (between 25 W and 100 W) in steps of 5 W with key **1**.
  - Define the length of time for the first stage (between 50 s and 250 s) in steps of 10 s with key **2**.
  - With key **3** the load increase (from 5 W to 50 W) in steps of 5 W from stage to stage is defined.

    After you enter the load increase, the time for each following stage will be automatically calculated by the unit.
  - If you require an ECG printout at the end of each stage , press key **4** and set to ON.
  - Key **5** defines the recovery load to which the ergometer returns as soon as the exercise test is interrupted. Set to any value between 40 and 145 W in steps of 5 W.
  - If you want to retain the protocol for future use, then press key **6**.

NOTE: *At the end of the exercise test a graphical representation of the relationship between heart rate and load will be displayed (see explanation for Conconi graph at the end of this chapter).*

TREADMILL SETTINGS

Preparations

- On the AT-10, ensure that the mains filter is activated.
- Ensure that the recording unit and the treadmill are connected to the same common ground.
- Ensure that the potential equalization stud is connected to common ground.

Connect Treadmill

The treadmill must be connected to the relevant socket(s) of the AT-10 (see Chp. 1, "External Connections").

- For **treadmills** of the **standard analogue type**, the 5-pin plug is connected to the "Ergo" interface and the 7-pin plug to the "DATA I/O" connection.
- **Digitally controlled treadmills** are connected to the RS-232 port 2.
- Connect the ergometer to the mains supply.

Select Treadmill

The treadmill must be selected in the exercise settings menu as follows:

- Key **1** selects the type of bicycle or treadmill to be used.

  The treadmill choices available for selection are:

  - **TM Analog 1** This is the normal setting to be selected when working with all standard types of treadmill.
  - **TM Analog 2** This setting should be selected when working with a normal (i.e. not high speed) Woodway treadmill (1 V = 3.2 km/h).
  - **TM Analog 2 HS** This setting should be selected when working with a high speed Woodway treadmill, i.e. with a maximum speed of up to 25 km/h (1 V = 6.4 km/h).
  - **TM RS-232 1** This setting is to be selected when working with the SCHILLER R9 treadmill.
  - **TM RS-232 2** This setting should be selected for the Powerjog treadmill model M10-S.
  - **TM TM-400S** This setting should be selected when working with the SCHILLER TM 400 S treadmill.

- Key **2** saves the settings made.

TREADMILL SETTINGS

Writing interval for Exercise Phase

To obtain an ECG printout during exercise phase at regular intervals, set the writing interval as follows:

- Press key **1** to define the duration of a treadmill pause. This setting enables a short pause to be entered between two stages during which the treadmill speed is returned to the initial speed, i.e. the speed defined for the pre-exercise phase (see next paragraph below). The available choices are: NO, 15, 20, or 30 seconds.

NOTE: The pause setting does not apply to the TM 400S treadmill type.

- Key **2** selects the writing interval **during the exercise phase**. The 'writing interval' indicates the intervals at which the ECG recording in the defined format 1 is printed out. The available choices are: OFF (no printout), 1 to 8 minutes and end of stage.

*NOTE: The writing interval during **recovery phase** is defined in the menu* EXERCISE *-3-6. Full details are given in the paragraph "Definition of Stage Printouts' later in this chapter.*

Warm-up and Recovery speed

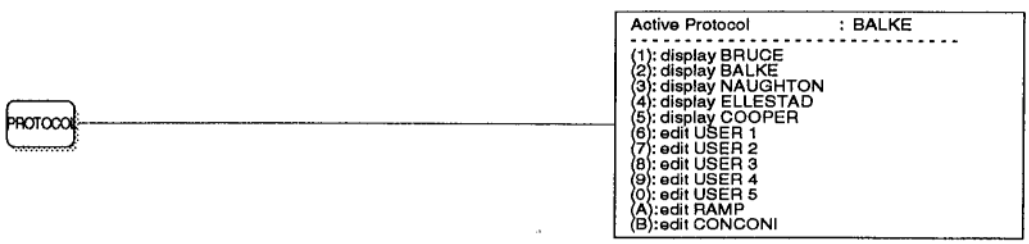
When conducting an exercise test with a treadmill, the speed for the warm-up (pre-exercise phase) and recovery stage (post exercise phase) can be predefined.

- Press key **3** in the above menu to define the treadmill speed to be maintained during the **warm up phase** (pre-exercise phase). Set to any value between 0.0 and 9.9 km/h (or 0.0 and 6.2 mph) in increments of 0.1 km/h (or mph).
- Press key **4** to define the treadmill speed to be maintained during the **recovery phase** (at the end of the exercise phase). Set to any value between 0.0 and 9.9 km/h (or 0.0 and 6.2 mph) in increments of 0.1 km/h (or mph).
- Press key **5** to save the settings.

TREADMILL SETTINGS

Select Protocol for Treadmill Test

Ensure that a treadmill type has been selected (EXERCISE -3-4-1).



Following protocols can be selected for the treadmill test:

- BRUCE
- BALKE
- NAUGHTON
- ELLESTAD
- COOPER
- USER 1 to USER 5
- RAMP
- CONCONI

NOTE: ***When displaying or editing a protocol it will automatically be selected as "active protocol" , i.e. this protocol will be applied for the treadmill test (in the example above the BALKE protocol has been selected for the test).***

Bruce

- Key **1** displays (and selects) the BRUCE protocol:

PROTOCOL: BRUCE			
STAGE	DUR	SPEED	GRADE
1	3 min	2.7 km/h (1.7 mph)	10.0 %
2	3 min	4.0 km/h (2.5 mph)	12.0 %
3	3 min	5.4 km/h (3.4 mph)	14.0 %
4	3 min	6.7 km/h (4.2 mph)	16.0 %
5	3 min	8.0 km/h (5.0 mph)	18.0 %
6	3 min	8.8 km/h (5.5 mph)	20.0 %
7	3 min	9.6 km/h (6.0 mph)	22.0 %

TREADMILL SETTINGS

Balke

- Key **2** displays the protocol of the BALKE test:

PROTOCOL: BALKE			
STAGE	DUR	SPEED	GRADE
1	2 min	5.0 km/h (3.0 mph)	2.5 %
2	2 min	5.0 km/h (3.0 mph)	5.0 %
3	2 min	5.0 km/h (3.0 mph)	7.5 %
4	2 min	5.0 km/h (3.0 mph)	10.0 %
5	2 min	5.0 km/h (3.0 mph)	12.5 %
6	2 min	5.0 km/h (3.0 mph)	15.0 %
7	2 min	5.0 km/h (3.0 mph)	17.5 %
8	2 min	5.0 km/h (3.0 mph)	20.0 %
9	2 min	5.0 km/h (3.0 mph)	22.5 %
10	2 min	5.0 km/h (3.0 mph)	25.0 %

Naughton

- Key **3** displays the protocol of the NAUGHTON test:

PROTOCOL: NAUGHTON			
STAGE	DUR	SPEED	GRADE
1	3 min	3.0 km/h (2.0 mph)	0.0 %
2	3 min	3.0 km/h (2.0 mph)	3.5 %
3	3 min	3.0 km/h (2.0 mph)	7.0 %
4	3 min	3.0 km/h (2.0 mph)	10.5 %
5	3 min	3.0 km/h (2.0 mph)	14.0 %
6	3 min	3.0 km/h (2.0 mph)	17.5 %

Ellestad

- Key **4** displays the protocol of the ELLESTAD test:

PROTOCOL: ELLESTAD			
STAGE	DUR	SPEED	GRADE
1	3 min	2.7 km/h (1.7 mph)	10.0 %
2	3 min	4.8 km/h (3.0 mph)	10.0 %
3	3 min	6.4 km/h (4.0 mph)	10.0 %
4	3 min	8.0 km/h (5.0 mph)	10.0 %
5	3 min	8.0 km/h (5.0 mph)	15.0 %
6	3 min	9.6 km/h (6.0 mph)	15.0 %

TREADMILL SETTINGS

Cooper

- Key **5** displays the protocol of the COOPER test:

PROTOCOL: COOPER			
STAGE	DUR	SPEED	GRADE
1	1 min	5.3 km/h (3.3 mph)	0.0 %
2	1 min	5.3 km/h (3.3 mph)	2.0 %
3	1 min	5.3 km/h (3.3 mph)	3.0 %
4	1 min	5.3 km/h (3.3 mph)	4.0 %
5	1 min	5.3 km/h (3.3 mph)	5.0 %
6	1 min	5.3 km/h (3.3 mph)	6.0 %
7	1 min	5.3 km/h (3.3 mph)	7.0 %
8	1 min	5.3 km/h (3.3 mph)	8.0 %
9	1 min	5.3 km/h (3.3 mph)	9.0 %
10	1 min	5.3 km/h (3.3 mph)	10.0 %
11	1 min	5.3 km/h (3.3 mph)	11.0 %
12	1 min	5.3 km/h (3.3 mph)	12.0 %

USER

- Keys **6, 7, 8, 9** and **0** display the user-defined protocols.

  The following example shows a user-defined protocol:

PROTOCOL: USER 1			
STAGE	DUR	SPEED	GRADE
1	1 min	3.0 km/h (2.0 mph)	0.0 %
2	1 min	3.0 km/h (2.0 mph)	5.0 %
3	1 min	3.0 km/h (2.0 mph)	10.0 %
4	1 min	3.0 km/h (2.0 mph)	15.0 %
5	1 min	3.0 km/h (2.0 mph)	16.0 %
6	1 min	3.0 km/h (2.0 mph)	17.0 %
7	0 min	3.0 km/h (2.0 mph)	18.0 %
8	1 min	3.0 km/h (2.0 mph)	20.0 %
9	1 min	3.0 km/h (2.0 mph)	21.0 %
10	1 min	3.0 km/h (2.0 mph)	22.0 %
11	1 min	3.0 km/h (2.0 mph)	23.0 %
12	1 min	3.0 km/h (2.0 mph)	24.0 %
G = save settings			

  - The duration, speed and grade can be altered as required by overwriting the value (numbers from 1 to 9 have to be entered as 01..09). Confirm with **ENTER** or with the direction keys.
  - The complete protocol can be stored for furture use by pressing key **G**.

NOTE: *To reduce the predefined number of stages, change the setting for the stage at which the exercise should stop to "0". The recovery phase will start at the end of the last active stage (stage 6 in the above example).*

TREADMILL SETTINGS

RAMP Protocol for Treadmill Test

During this test the patient should attain a predefined **target** value within a certain amount of time. This target value is based upon the metabolic equivalents (METS) . Following is a brief explanation of the METS concept.

Metabolic Equivalents (METS)

The metabolic equivalents, or METS, provide a simple means of determining energy expenditure during exercise.

The provision of a MET value for each stage of an exercise test assists in determining the exercise tolerance of a patient in conjunction with factors such a weight, degree of fitness, sex and age.

Definition of METS

1 METS = 3.5 ml of O_2 per minute per kilogram of body weight

One Met is defined as the resting metabolic rate, i.e. the amount of oxygen consumed by the patient while seated at rest. As such, an individual exercising at two METS requires twice , at three METS three times the resting metabolism.

For a standard stress test without gas exchange measurements, the METS value will be calculated on the basis of an approximation formula . The calculated value may hence differ from the actually measured value.

Formula applied

V < 8 km/h
$METS = \frac{V \cdot 1.675 + 0.3015 \cdot V \cdot G + 3.5}{3,5}$

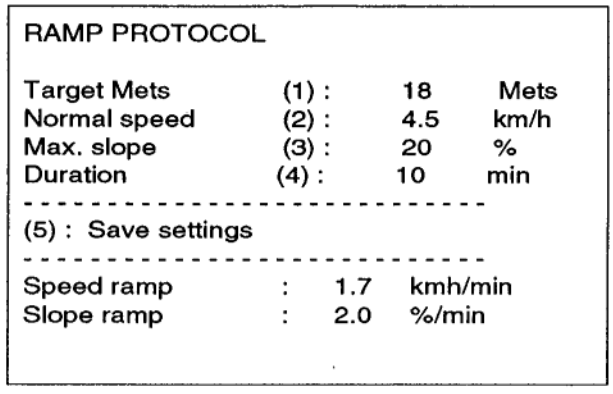
V ≥ 8 km/h
$METS = \frac{V \cdot 3.35 + 0.15075 \cdot V \cdot G + 3.5}{3,5}$

V = treadmill speed

G = treadmill elevation

TREADMILL SETTINGS

- Key A displays the RAMP protocol:


RAMP PROTOCOL
Target Mets (1) : 18 Mets
Normal speed (2) : 4.5 km/h
Max. slope (3) : 20 %
Duration (4) : 10 min
(5) : Save settings
Speed ramp : 1.7 kmh/min
Slope ramp : 2.0 %/min

- Define the parameters for the test which the patient should accomplish, i.e. attaining the target value (target Mets) within the time period defined (duration).
- Once the values have been entered (with the keys 1 to 4) the increases in speed (speed ramp) and elevation (slope ramp) will be calculated by the unit. In the bottom section of the menu screen following data is then displayed:
  - the rate at which the speed will increase per minute (indicated at "speed ramp" in kph/min or mph/min),
  - the rate at which elevation will increase per minute (indicated at "slope ramp" in %/min).

  Preselection of ramp parameters:
  - Press key **1** to set "**Target Mets**" to any value between 4 and 30 in increments of 1. **Target Mets** refers to the metabolic equivalents (METS).
  - Press key **2** to set "**Normal speed**" to any value between 4.0 and 16.0 km/h (or 2.5 and 10.0 mph) in increments of 0.1 km/h (or mph).

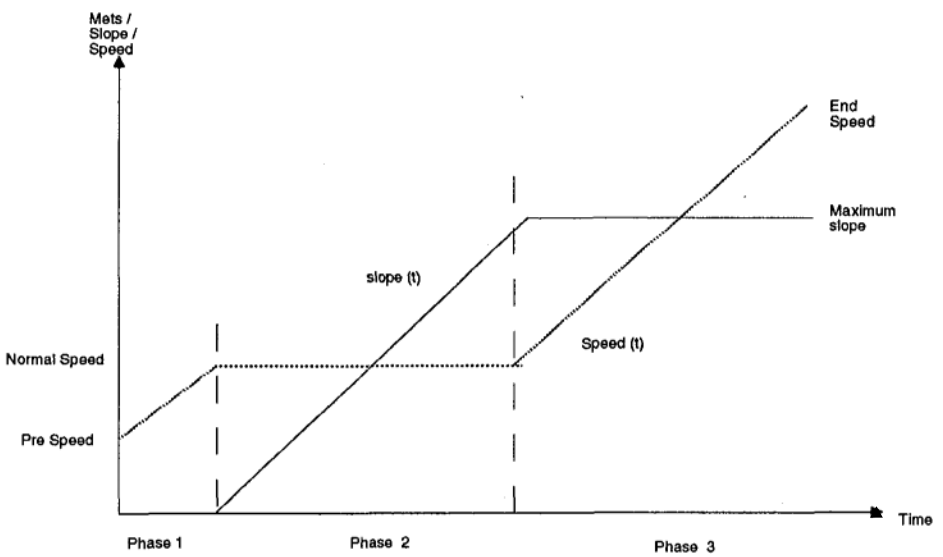
NOTE: *Treadmill speed during warm-up phase should not be lower than 1.8 km/h (1.1 mph) or higher than 6.4 km/h (4 mph) . To set this speed press* **EXERCISE** *-3-5-3).*

- Key **3** selects the "**Maximum slope**" of the treadmill. Set to any value between 20 and 25% in increments of 1%.
- Key **4** selects the "**Duration**". Set to any value between 5 and 20 minutes in steps of 1. **Duration** determines the time period during which the target METS should be achieved.
- Press key **5** to save the settings made and to retain them for future use.

TREADMILL SETTINGS

Example of a ramp test using the above menu settings:

The patient should achieve 18 METS within 10 minutes. The value selected for normal treadmill speed is 4.5 km/h and the maximum percent of incline of the treadmill is 20%. Warm-up speed during pre-exercise has been set to 3.5 km/h (**EXERCISE** -3-5-3).



A ramp test is carried out in 3 phases:

Phase 1: Treadmill speed is gradually increased from 3.5 km/h to 4.5 km/h (the value defined for **normal speed**). The percent of incline is 0.

Phase 2: The elevation of the treadmill increases from 0% to 20% in a continuous mode. Treadmill speed remains constant at 4.5 km/h.

Phase 3: Once the **maximum slope** is attained, treadmill speed starts to increase again. It does not stop to increase until the target METS value has been achieved.

10 minutes have elapsed from the time the ramp test was started up to the time the target METS were achieved.

TREADMILL SETTINGS

Conconi Protocol

- Key **B** in the protocol menu displays the CONCONI protocol. The following is a typical example of a Conconi protocol:

Treadmill CONCONI-Test

Start speed (1): 6.0 km/h
Speed Augmentation (2): 0.6 km/h
Report at stg. end (3): OFF

(4): Save settings

Stage	Time from beginning	Duration of stage	Speed
1:	0 s	118 s	6.0 km/h
2:	118 s	111 s	6.6 km/h
3:	229 s	100 s	7.2 km/h
4:	329 s	91 s	7.8 km/h
5:	420 s	87 s	8.4 km/h
6:	507 s	80 s	9.0 km/h
7:	587 s	74 s	9.6 km/h
8:	661 s	71 s	10.2 km/h
9:	732 s	67 s	10.8 km/h
10:	799 s	63 s	11.4 km/h
11:	862 s	61 s	12.0 km/h
12:	923 s	57 s	12.6 km/h

The Conconi test is based on a constant work output over each stage. When the speed of the treadmill is increased, the stage time is decreased so that the work output coefficient remains constant (as calculated on the first stage).

- Enter the start speed (between 2.5 km/h [or 1.56 mph] and 18.0 km/h [or 11.25 mph] in steps of 0.5 km/h [or 0.31 mph]) with key **1**.
- With key **2** the speed increase (from 0.1 km/h [or 0.062 mph] to 2.0 km/h [or 1.25 mph]) in steps of 0.1 km/h [or 0.062 mph] from stage to stage is defined.

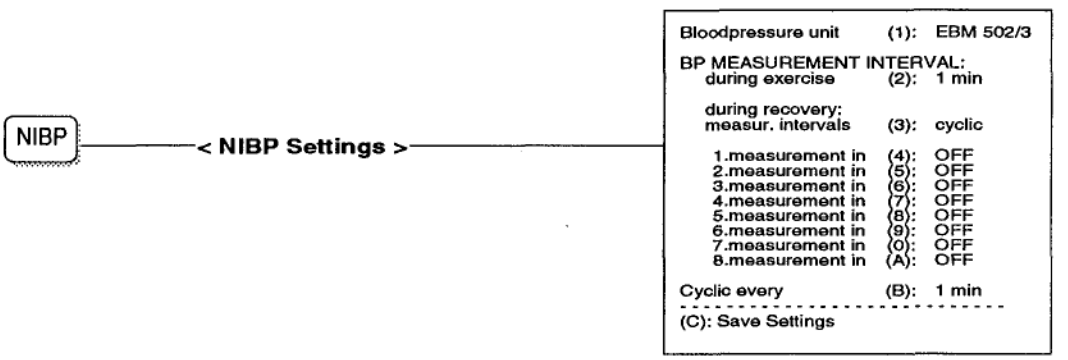
  Once the increase has been entered, the time for each following stage is automatically calculated by the unit.
- To obtain an ECG printout at the end of each stage, press key **3** and set to ON.
- Save the settings with key **4**.

AUTOMATIC BLOOD PRESSURE MEASUREMENTS

In order to take automatic blood pressure readings at regular intervals throughout the exercise test, a suitable blood pressure measuring unit has to be connected to the AT-10.

Set Options for Blood Pressure Measurements

Enter the respective menu as follows:



- Press key **1** to select one of the following options:
  - **NO** no unit selected
  - **EBM 502/3** Model EBM 502 or 503 from Bosch, Ergoline 900
  - **PARA 9300** Model PARA 9300 from Paramed
- Press key **2** to define the measurement interval during the **exercice phase**. Set to OFF or any value between 1 and 8 minutes or to end of stage (measurement at the end of each stage).
- Key **3** defines the measurement intervals during the **recovery phase**. Select between cyclic and user-defined intervals. When blood pressure readings should be taken at regular intervals set to "cyclic". When you wish to take blood pressure measurements at individual intervals set to "user-defined". This option permits to define up to 8 individual intervals.
  - Press keys **4 - 9, 0** and **A** to define the individual intervals. These can be set to any value between 1 and 12 minutes or to OFF.

    OR
  - Press key **B** to define the cyclic interval. Set to any value between 1 and 8 minutes or to OF.
- Press key **C** to save the settings for future use.

Connect Patient

Apply the cuff to the patient's upper arm.

Connect the blood pressure measuring unit to the RS-232 port 1 situated on the side panel of the AT-10.

The AT-10 will now automatically initiate blood pressure measurements at the preset intervals throughout the course of the exercise test. The systolic and diastolic values are given on the periodic ECG printout and on the display. In the final report, the measurement results are presented as a diagram.

NOTE: The measurement results remain available on the screen for a period of two minutes. If measurements follow at short intervals, the values are held in display until updated by the next automatic measurement.

EXERCISE SETTINGS

Target Heart Rate

Before each test, the heart rate alarm limit has to be set. This setting enables the automatic initiation of an acoustic alarm as soon as the heart rate limit is reached during the course of the exercise test.

Once the stress test has been started, the alarm limit will be displayed in parenthesis in the upper left corner of the screen next to the heart rate.

IMPORTANT

THE PATIENT DATA, IN PARTICULAR THE DATE OF BIRTH, MUST HAVE BEEN ENTERED.

To set the limit, enter the following menu:

- Key **1** selects the appropriate calculation mode for the heart rate limit. The following selections can be made:
  - No Alarm
  - 220 – age
  - 90% of 220 – age
  - 200 –age
  - m: 205 – 1/2 age f: 220 – age
    (m = male: 205 minus half the patient's age)
    (f = female: 220 minus patient age)
  - Manual input:
    This option allows for any heart rate alarm setting to be defined within the range of 100 to 250 beats/min.
- Press key **2** and select the appropriate value (in steps of 1) with the **+** or **-** key or set to "0" (no alarm).
- Key **3** saves the settings.

NOTE: *If you selected an **automatic calculation mode**, the heart rate alarm limit will be calculated automatically for any new patient for which data has been entered. If you selected manual input or changed an automatically calculated value, only the last indicated value will be retained. Regardless of the settings made in this menu, only the formula **"220 - age"** or **"m:205-1/2 age f: 220 - age"** will be applied in the final report to give the percentage that the maximum heart rate achieved during the test is of the maximum calculated heart rate.*

EXERCISE SETTINGS

ST Measurement Point

During the exercise test, the ST amplitude is measured continuously. The position of the amplitude measurement point in the ST segment can be freely defined by the user.

NOTE: *The selected measurement point appears in the ECG measurement table as "Jxx" and "Jxxn" (e.g. "J40" and "J40n").*

Enter the menu as follows:

- Press key **1** to set the measurement point to the desired temporal distance from the J point (00 to 80 ms in steps of 10).

NOTE: The menu option 2 can only be selected when the optional EXEC programme (analysis programme for exercise ECGs) is installed in the unit .

- Key **3** saves the settings made.

DEFINITION OF FINAL REPORT

In this menu the information that is given on the final report is defined (when key PRINT REPORT is pressed at the end of a stress test). To define the print format for the final report, enter the following menu:

NOTE: Without EXEC only the rhythm option can be defined in this menu.

EXERCISE —< **Exercise Settings** >—< **Format Final Report** >—

FORMAT FOR FINAL REPORT	
ST-Trends	(1): YES
ST-HR Diagrams	(2): NO
Interpretation	(3): NO
Average Cycles	(4): COMPACT
Speed	(5): 50 mm/s
Channels	(6): 6
Rhythm (R1)	(7): NO
Speed	(8): 12.5 mm/s
Sensitivity	(9): NORMAL
CAD-Probability	(0): NO

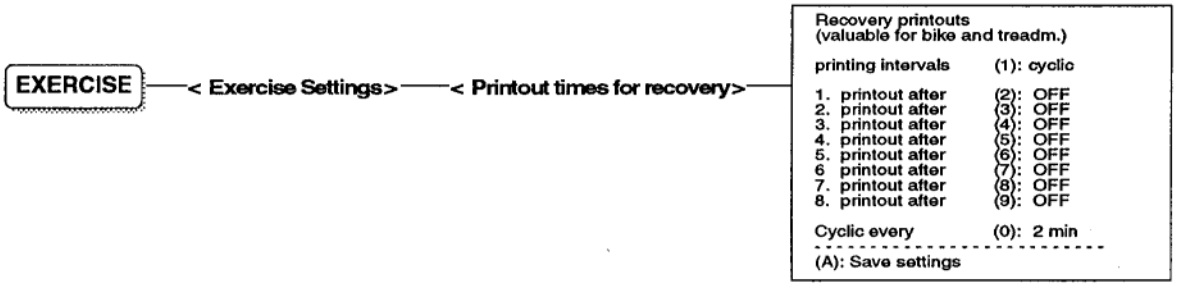
ST Trends	Set to YES (print) or NO (suppress printing).
ST-HR Diagram	Set to YES (print) or NO (suppress printing).
Interpretation	Print interpretation statement. Set to YES (print) or NO (suppress printing).
Average Cycles	Print Average cycles. Select COMPACT, ALL or NO
	Printing speed (for average cycles when 'Compact' or 'All' selected above). Set to 25 or 50 mm/s.
	Number of channels on printout (for average cycles when 'Compact' or 'All' selected above). Set to 6 or 12 channels.
Rhythm (R1)	Print rhythm lead R1 YES or NO.
	Rhythm lead R1 is selected in the rhythm menu (**ECG** -1-1-1).
	Printing speed (for rhythm strip when Rhythm selected YES above) . Set to 6.25 or 12.5 mm/s.
	Sensitivity (amplitude) (for printout of rhythm strip when Rhythm selected YES above) . Set to NORMAL (10 mm/mV) or HALF (5 mm/mV)
CAD-Probability	1-page printout. Set to YES (print) or NO (suppress printing).
	NOTE: This option is not available in the U.S.A.

DEFINITION OF STAGE PRINTOUTS

Writing Intervals

During the **exercise phase** , periodic printouts in the defined auto format 1 are obtained at the preset intervals.

To also obtain regular printouts during the **recovery phase**, set the writing interval as follows (applies to bicycle and treadmill):



- Press key **1** to select between cyclic and user-defined intervals. To obtain periodic printouts at regular intervals set to "cyclic". If you wish to obtain printouts at individual intervals set to "user-defined". This option permits to define up to 8 individual intervals.
  - Press keys **2 -9** to define the individual intervals. These can be set to any value between 1 and 12 minutes or to OFF.

    OR
  - Press key **0** to define the cyclic interval. Set to any value between 1 and 8 minutes or to OF.
- Press key **A** to save the settings for future use.

Periodic Printout Information

NOTE: *Certain information (i.e. measurements) is only available if the required software option is installed.*

Throughout the course of the testing, automatic printouts will be produced periodically in accordance with the writing interval set. Each periodic printout comprises the following information:

- Patient data
- MTA identification
- Date and time of the recording
- Exercise test data with:
  - Mean heart rate (HR) in beats per minute (BPM)
  - Mean duration of the QRS complex in ms (QRS) measured from its onset to the ST segment onset
  - Mean QRS complex axis
  - Mean systolic and diastolic blood pressure (BP) values
  - Manually entered rating for symptoms (P = chest pain, Y = dyspnea, D = dizziness)
  - Speed (km/h or mph), if a treadmill is used
  - Load (in W), if a bicycle is used
  - Elevation (in %), if a treadmill is used
  - Metabolic equivalents (METS), if a treadmill is used
  - Number and duration of actual stage
  - Time from the start of the exercise test

DEFINITION OF STAGE PRINTOUTS

Periodic Printout Information (cont'd)

- ECG leads in accordance with the settings made for printout format 1
- Average QRS in accordance with the settings made for printout format 1
- ECG measurement (if selected)
- Information about settings at which the ECG was taken is listed at the bottom of the periodic printout such as:
  - Sensitivity (mm/mV)
  - Speed (mm/s)
  - Filter settings
  - Unit identification
  - Code for software options installed in the unit (e.g. "C" for interpretation)
  - Software version
  - User identification

DEFINITION OF STAGE PRINTOUTS

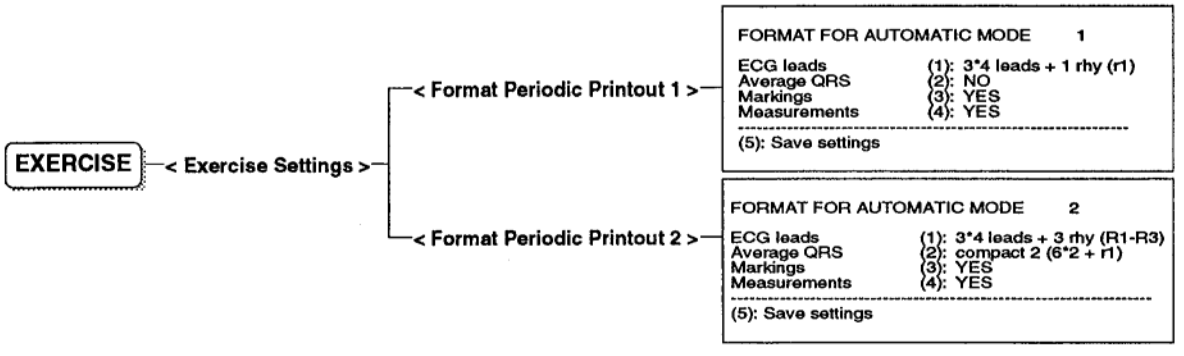
Set Format 1 or 2

There are several settings which can be made for automatic mode recording which determine the format and content of the printout. For the documentation of the test results during the test, two periodic printout formats (1 and 2) can be programmed.

Once programmed, there are several ways to obtain a printout:

- Periodic printouts during exercise and recovery phase at preset intervals. *In format 1 only.*
- Extra printouts at any time during the testing of the last 10 seconds of evaluated ECG data:
  - In format 1 press AUTO START.
  - In format 2 press 2ND followed by AUTO START.
- Extra copies of periodic printouts at any time during the exercise testing:
  - In format 1 press COPY.
  - In format 2 press 2ND followed by COPY.

To define the format for the periodic printouts 1 or 2 select one of the menus as follows:



DEFINITION OF STAGE PRINTOUTS

In both configurations (Automatic Mode Format 1 and 2) the following selections can be made:

ECG Leads

The configuration of the printed leads is determined by pressing key '**1**' as follows:

NO No leads are printed.

*3*4 leads + 1 rhy. (r1)* 12 leads (4 columns with 3 ECGs each) and one rhythm strip (user programmed lead r1) are printed.

*3*4 leads + 3 rhy. (R1-R3)* 12 leads (4 columns with 3 ECGs each) and three rhythm strips (user programmed leads R1, R2 and R3) are printed.

SHORT: 25 mm/s 12 leads are printed in "short" format; i.e. over 1 page , at a chart speed of 25 mm/s.

SHORT: 50 mm/s As before, but chart speed 50 mm/s.

SHORT: 100 mm/s As before, but chart speed 100 mm/s.

LONG: 25 mm/s 12 leads* are printed in "long" format; i.e. over 2 pages, at a chart speed of 25 mm/s.

LONG: 50 mm/s As before, but chart speed 50 mm/s.

LONG: 100 mm/s As before, but chart speed 100 mm/s.

When SHORT or LONG formats are selected, pressing PRINTER CHANNEL *alters the layout of the print-out:*

3 channels => 4 columns of 3 ECG leads
6 channels => 2 columns of 6 ECG leads

LONG formats print twice as many heart beats as the SHORT format.

Progr. leads print as many channels as configured by pressing the key "PRINTER CHANNEL"

prog. leads 25 mm/s Individually user defined leads printed at a chart speed of 25 mm/s.

prog. leads 50 mm/s As before, but chart speed 50 mm/s.

prog. leads 100 mm/s As before, but chart speed 100 mm/s.

prog. leads (25 mm/s, 5 s) The last 5 seconds of user defined leads with a chart speed of 25 mm/s.

DEFINITION OF STAGE PRINTOUTS

Average QRS

Only available if either Interpretation (i) or Measurement (M) option is installed.

The configuration of the printed leads is determined by pressing key '**2**' as follows:

NO No average cycles are printed.

*Compact 1 (3*4 + R1,R2,R3)* The average QRS cycles of the 12 leads (4 columns with 3 ECGs each) and three rhythm leads are printed on one page at a chart speed of 25 mm/s.

*Compact 2 (6*2 + r1)* The average QRS cycles of the 12 leads (2 columns with 6 ECGs each) and 1 rhythm lead (user programmed lead r1) are printed on one page.

*2*6 leads + 3*rhy. (R1-R3)* The average QRS cycles of the 12 leads (6 columns with 2 ECGs each) and three rhythm leads are printed.

*3*4 leads + 1*rhy. (r1)* The average QRS cycles of the 12 leads (4 columns with 3 ECGs each on two pages) and 1 rhythm lead (user programmed lead R1) are printed.

Markings

(for Average QRS) - *Only available if either Interpretation (i) or Measurement (M) option is installed.*

Pressing key '**3**' provides vertical reference marks at the beginning and end of the P wave and QRS complexes and at the end of the T wave. These marks can be added (YES) or omitted (NO).

Measurements

Only available if either Interpretation (i) or Measurement (M) option is installed.

The ECG measurements contains a printed table of the amplitude value and the time length for each of the 12 leads.

Pressing key '**4**' provides a measurement table of all important parameters at the end of the printout. The table can be included (YES) or omitted (NO).

Full details of the Measurement option is given in the SCHILLER ECG Measurement and Interpretation Booklet (art. no. 2.510 179).

To save the settings made, press key **5**. Confirmation is given by the indication

* * * Settings memorized! * * *

COMMENCING THE TEST

Start Exercise Test

The exercise test with periodic printouts is started by pressing the BEGIN TEST key.

A complete ECG will be printed out at the preset intervals .

NOTE: *The settings made for the printout format 1 (EXERCISE -3-1) determine the layout of the printout.*

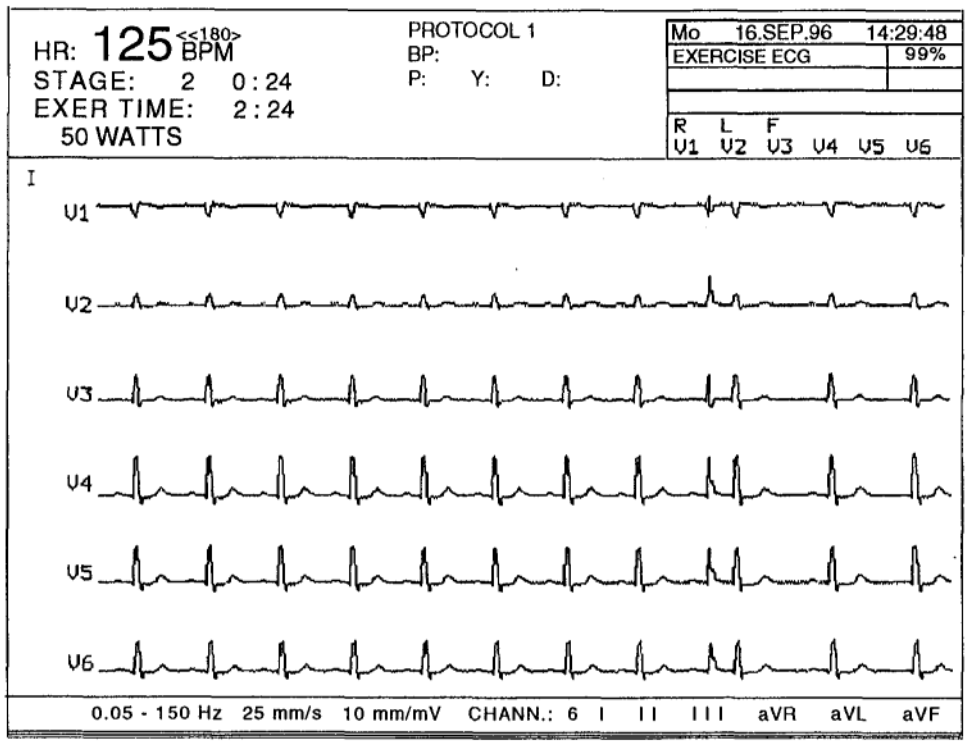
CAUTION: ***STARTING THE EXERCISE TEST WILL DELETE EXISTING FILES IN THE UNIT'S INTERNAL DATA MEMORY.***

A warning message will appear on the screen if any stored files have been found. Check if you still need these files and transfer them to another unit or PC as appropriate. For further details on how to transfer or delete stored files, please refer to Chapter 5.

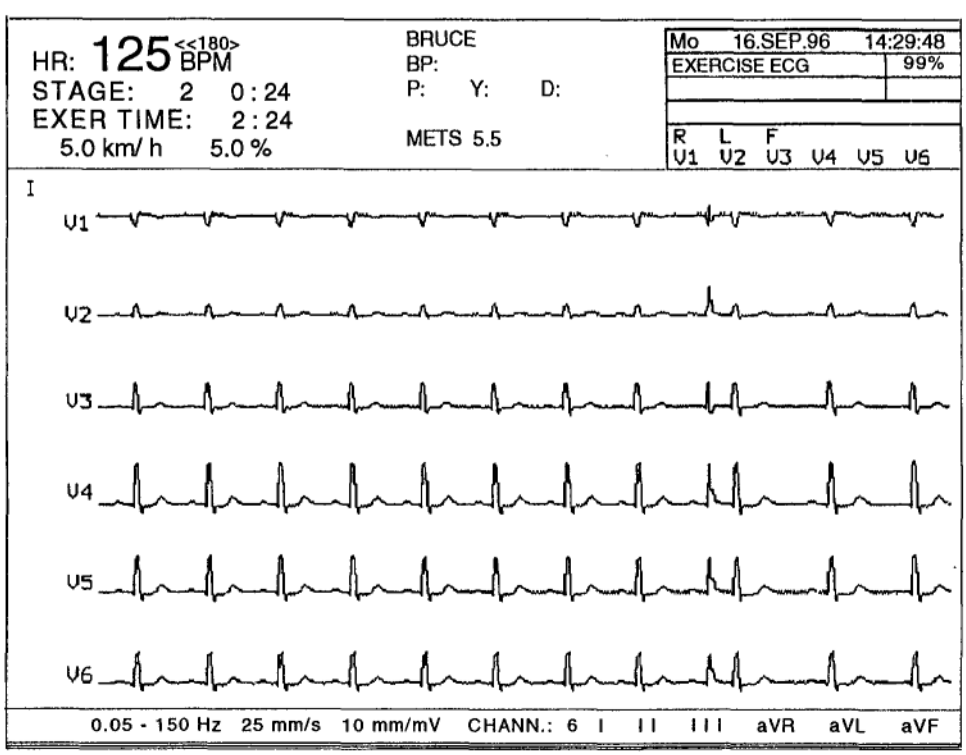
DURING THE TEST

Information Displayed for a Bicycle Test (without EXEC):

The following example shows the display for a test with a bicycle ergometer:



Information Displayed for a Treadmill Test (without EXEC):



DURING THE TEST

Explanation of Displayed Information:

Upper Left Part of Screen

In the upper left of the screen following data is displayed and continually renewed:

- Heart rate HR (target heart rate in parenthesis)
- Stage identification and duration in h:min
  - P = pre-exercise phase (warm-up phase)
  - 1...99 = load step (exercise phase)
  - R = recovery phase (resting phase)
- Time from start of the exercise phase in h:min
- Ergometer-related test data:
  - for a bicycle: load in Watts
  - for a treadmill: speed in km/h (or mph) and grade in %

Upper Middle Part of Screen

In the upper middle part of the screen following data is displayed:

- Protocol identification
- Blood pressure values (automatically measured or manually entered).
- Manually entered ratings for symptoms
- For a treadmill test the metabolic equivalents are also given.

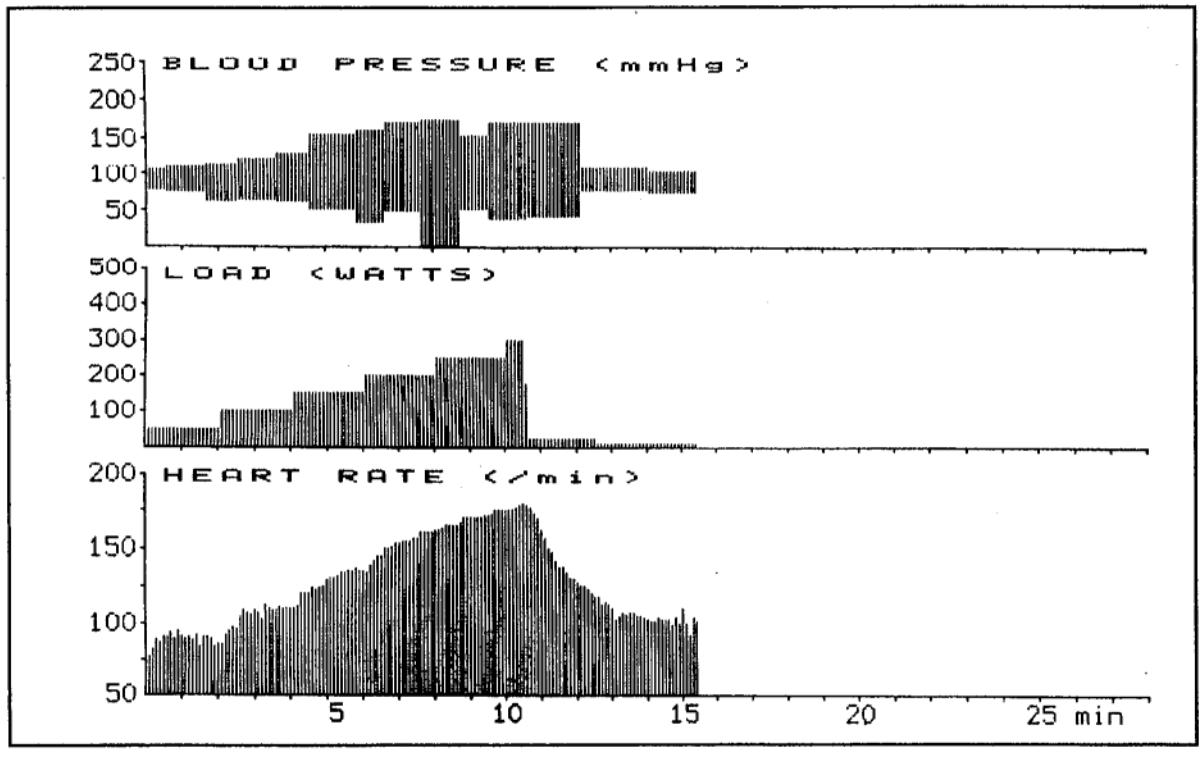
DURING THE TEST

Display Trend Plots

As soon as the exercise test has been started , you can switch the display to give trend plot diagrams for blood pressure, load (or speed and elevation) and heart rate.

- Press the CHANGE SCREEN key to toggle the display. Press this key again to return to the normal ECG representation.

The trend plots are displayed as in the following example:



DURING THE TEST

Customize Display

Changing the Number of Display Channels

When the unit is switched on, it always remembers the last display configuration selected before switching off.

- By pressing the key MONITOR CHANNEL the display toggles between **3, 6 or 8 channels.**

Depending on the number of channels selected, the leads are displayed as follows (standard lead sequence):

- 3 channel mode: I II III
- 6 channel mode: I II III aVR aVL aVF
- 8 channel mode: II III V1 V2 V3 V4 V5 V6

Changing the Lead Group

In the **8-channel mode**, the lead grouping is fixed and cannot be changed.

In **3 or 6-channel mode** you can change the lead groups at any time by making new selections with the lead keys.

- Press the lead keys LEAD ◁ LEAD ▷ to display the next or preceding lead group.

NOTE: *Lead groups can be changed at any time during the recording.*

Changing Sensitivity and Speed of the Monitor Display

- By pressing the key MONITOR mm/mV the signal amplification is switched between the following values:
  - 5 or 10 mm/mV with 3 leads displayed,
  - 2.5 or 5 mm/mV with more than 3 leads displayed.

  The amplitude of the 1 mV pulse displayed to the left of the first lead indicates the sensitivity selected.

- By pressing the key MONITOR mm/s the display speed is switched between 12.5, 25 and 62.5 mm/s. The time reference is given on the bottom of the screen indicated by '1s' and a series of points, the time difference from point to point is 1 sec.

The above values represent the ECG size and speed on the printout initiated with the PRINT SCREEN key (see below).

DURING THE TEST

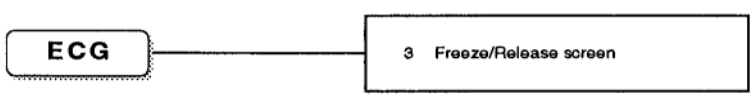
Inserting a Calibration Signal

- By pressing the key [1 mV] a square wave 1 mV calibration signal can be manually inserted into the recorded signals.

The amplitude of the square wave pulse depends on the sensitivity selected with the [MONITOR mm/mV] key.

Freeze/Release Display

The ECG signals displayed on the screen can be "frozen" at any time for closer examination as follows:



The recording of the ECG continues while the screen is frozen.

Print Screen

- [PRINT SCREEN] prints the screen as displayed.

Obtaining Extra Printouts during the Test

Extra Printouts in Format 1 or 2

- Press the [AUTO START] key at any time during the test to obtain an extra printout in format 1 of last 10 seconds of the recorded and evaluated ECG data.
- Press key [2ND] followed by [AUTO START] to obtain an extra printout in format 2 (last 10 seconds) at any time during the test.

Extra Copies in Format 1 or 2

- By pressing the [COPY] key you get a copy of the last periodic print-out in format 1.
- Press key [2ND] and then [COPY] to get a copy of the last periodic printout in format 2.

DURING THE TEST

Individual Blood Pressure Measurements

Manual Entry of Blood Pressure Values

If blood pressure measurements are made independently of the electrocardiograph and the ergometer, then the results can be manually entered in the following menu:

The cursor is ready for the entry of the systolic and diastolic values.

- Enter the systolic values followed by a blank, full stop or comma.
- Now enter the diastolic value and confirm the complete entry by pressing ENTER.

The information entered will appear both on the display and on the periodic ECG printout.

NOTE: *The values remain available on the screen for a period of two minutes.*

Additional Measurements During Interval Mode

During exercise testing with automatic blood pressure measurements at preset intervals you can carry out additional measurements as desired at any time as follows:

Once this displays appears, the cuff will automatically inflate and deflate for blood pressure reading. The results are given as follows:

- SYS: Systolic pressure
- DIA: diastolic pressure
- MAP: Mean arterial pressure
- DIF: Difference between systolic and diastolic pressure
- PULS: Pulse
- SYS*P: Pumping capacity of the heart during 1 minute (systolic pressure multiplied by the pulse rate)

DURING THE TEST

Manual Ergometer Control during Automated Operation

The ergometer control keys on the alphanumeric keyboard allow you to take control of the test and change the automated procedure at any time.

Holding Load Stage

The duration of any stage of exercise can be extended beyond the preprogrammed duration at any time during the test.

- Press the key [HOLD STAGE] to maintain the current stage. The bicycle load (or treadmill speed and elevation) will remain constant and staging will not occur until the "hold" mode is released.
  - Confirmation that the stage has been held is given in form of the letter "H" which appears at the top of the screen underneath the total exercise duration time. The automatic switching to the next stage at the end of the programmed interval is overridden and the current load stage is maintained.
- To release the program from its hold stage for immediate advancement to the next stage according to the selected protocol, press the key [NEXT STAGE].

Bicycle Control

At any time during the test, you can manually advance to the next stage of the protocol. This can only be done, however, after the first 20 seconds of the pre-exercise phase have elapsed.

- Press the key [NEXT STAGE] to **advance to the next load step.**

The programmed load for a particular stage can be changed by manually increasing or decreasing the current value.

- To **change the load,** first press the key [SPEED LOAD]. By pressing the keys [NO −] or [YES +] the load can be increased (up to a maximum of 500 W) or decreased in increments of 5 W.

The current load is indicated in the top left of the screen.

NOTE: *Not all bicycles are capable of increasing to the maximum load of 500 W. Please consult the ergometer documentation for details.*

DURING THE TEST

Manual Ergometer Control during Automated Operation (Cont.)

Treadmill Control

At any time during the test, you can manually advance to the next stage of the protocol. This can only be done, however, after the first 20 seconds of the pre-exercise phase have elapsed.

‹ Press the key [NEXT STAGE] to **advance to the next stage.**

Treadmill elevation and speed as programmed for a particular stage can be changed by manually increasing or decreasing the current values.

- To **alter the elevation,** first press the key [GRADE].

  - By pressing the keys [NO −] or [YES +] the elevation can be increased (up to a maximum of 25%) or decreased in increments of 0.5%.
  - By pressing key **2**, the current elevation will be reset to zero until the beginning of the next stage.

- To **alter the speed,** first press the key [SPEED LOAD].

  - By pressing the key [NO −] or [YES +] the speed can be increased (up to a maximum of 25 km/h or 15.6 mph) or decreased in increments of 0.1 km/h (or mph).
  - By pressing key **2**, the current speed will be reset to zero until the beginning of the next stage.

The current elevation and speed are indicated in the top left of the screen.

NOTE: *Not all treadmills are capable of increasing to the maximum speed of 25 km/h (or 15.6 mph). Please consult the treadmill documentation for details.*

NOTE: *"Hold" and "Next stage" can also be applied for the CONCONI test, however "Grade" and "Speed/load" are not applicable.*

DURING THE TEST

Enter Symptom Ratings

During the test, subjective patient symptoms can be entered according to their severity.

To enter this data, press the key

to display the following:

ASSESSMENT OF SYMPTOMS		
Chest pain	(1):	0 /31
Dyspnea	(2):	0 / 31
Dizziness	(3):	0 / 63

Enter a value between 0 and 31 (for chest pain and dyspnea) and a value between 0 and 63 (for dizziness).

- Enter the desired values and confirm each entry by pressing the **ENTER** key.
  (The values entered here will appear both on the screen and on the periodic printout.)
- To reset a value to zero, press the slash key "/". The value is then reset to the standard setting - in this case 0.

NOTE: *To display the symptoms along with their assigned values both on the screen and on the printout after the stress test has been started, it is necessary that at least for one symptom a value has been entered.*

TEST INTERRUPTION

Interrupting the Test

When you note that the patient is unable to continue the test or if a **criteria for interruption** indicates that the exercise phase should be terminated, press the [RECOVERY] key to interrupt the test.

For a bicycle test, this key must always be activated to end the exercise phase and start the recovery phase.

For a treadmill test, the exercise phase usually continues until the end of the last stage of the selected protocol. The recovery phase starts automatically when using one of the standard or user-defined treadmill protocols. To interrupt the test at any time press the [RECOVERY] key. The ergometer gradually reverts to the defined recovery load or speed and the results of the last protocol stage are given in form of a '**PEAK EXERCISE**' printout. During the time this peak exercise protocol is printed, the criteria for interruption are displayed (see next paragraph).

At any time during the recovery phase you can control the ergometer functions. Press the key [HOLD STAGE] when you wish to maintain the ergometer at the present load or speed (the letter "H", designating "hold mode", will appear). While in this hold mode, you may also alter the load or speed by pressing the key [SPEED / LOAD]. The current load or speed will be displayed on the screen. When using a bicycle, increase or decrease the load with the key [YES +] or [NO −], in crements of 5 Watts. When using a treadmill, change the speed in the same way (in crements of 0,1 km/h or 0,1 mph). By pressing key **2**, the treadmill will come to an immediate stop.

Press key [NEXT STAGE] to revert to the normal recovery process.

Heart rate and blood pressure measurements continue while the patient recovers. To complete the test, the final report has to be printed out.

TEST INTERRUPTION

Criteria for Interruption

Select Criteria

During the time the peak exercise protocol is printed, the criteria for interruption are displayed:

```
END POINT CRITERIA          '2nd E' = edit
  0 = CHEST PAIN
  1 = DIZZINESS
  2 = DYSPNEA
  3 = ECG CHANGES
  4 = ARRHYTHMIA
  5 = FATIGUE
  6 = TARGET HR ATTAINED
  7 = BP BEHAVIOR
  8 = DECREASED HR DURING EXERCISE
  9 = DECREASE OF BP

'2nd D' = Default criteria
```

The criteria shown in this table are the default criteria.

To indicate the causes for the interruption in the final report, you have to selected the criteria.

- Press the number(s) displayed to select the criteria. An asterisk **(*)** will mark the selection.
- Confirm by pressing the **ENTER** key.

NOTE: *You can select several criteria, in the final report only the first three will appear.*

Change Criteria

An editing function allows you to change the criteria shown in the table or to define new ones. To call up the editing function, press the 2ND key followed by **E**.

NOTE: *The CAPS keys must be activated.*

TEST INTERRUPTION

The table with the criteria and the editing functions appears as follows:

```
END POINT CRITERIA          '2nd S' = save
  0 = CHEST PAIN
  1 = DIZZINESS
  2 = DYSPNEA
  3 = ECG CHANGES
  4 = ARRHYTHMIA
  5 = FATIGUE
  6 = TARGET HR ATTAINED
  7 = BP BEHAVIOR
  8 = DECREASED HR DURING EXERCISE
  9 = DECREASE OF BP

  '2nd >'   '2nd <'   '2nd W'   '2nd DEL'
```

The editing functions are:

◁ ▷ moves cursor one position to the left/right

△ ▽ moves the cursor one position up/down

DEL deletes character to the left of the cursor

2ND + ◁ moves cursor to the beginning of the line

2ND + ▷ moves cursor to the end of the line

2ND **+ W** deletes the word where the cursor is positioned

2ND **+ DEL** deletes the line where the cursor is positioned

- **ENTER** Line break at cursor position. Moves the text entry point to the beginning of the next line.

- To save changes, press the key 2ND and then key **S**.

Display Default Criteria

- Press key 2ND and then key **D** to restore the default criteria.

FINAL REPORT

- Press the key PRINT REPORT to complete the recovery phase and initiate printout of the final report.

NOTE: *With the EXEC option installed, a more comprehensive final report will be printed out.*

Final Report for Bicycle Ergometer

A test with a bicycle is documented containing the following information in the final report:

- Trend plots of blood pressure, load and heart rate
- Test data with:
  - Base Load
  - Load step and step interval
  - End exercise period (time from the start of the exercise phase until the beginning of the recovery phase)
  - End of stress test (total duration of test from start of exercise phase)
  - Max. heart rate achieved and percentage that this rate is of the maximum calculated heart rate (calculated on the basis 220 - age or m: 205 - 1/2)
  - Physical working capacities (PWC max., PWC 150/170, PWC rel.)

    => For the USA, the 'PWC max.' value in percent of the predicted work performance will not be given.
  - Max BP (highest systolic and lowest diastolic pressure achieved)
  - Max BP (syst)* HR (this figure is derived by multiplying the highest heart rate achieved by the systolic blood pressure at that time)
  - Criteria for interruption (maximum number of 3)
- Patient data
- Date and time

The final report may include other information not listed above. Options are selected in the menu **EXERCISE** -3-3.

Physical Working Capacity (PWC)

The PWC value is an indicator of the physical working capacity at a specific heart rate. Following is an explanation of the PWC values given on the final report.

PWC max.

- The maximum load in Watts achieved by the patient as compared to the predicted maximum work performance.

  Example: PWC max: 150 W = 78% signifies the following:

  - maximum load in Watts achieved by the patient: 150W
  - predicted work performance for this patient calculated on the basis of the formula below: 192W
  - 78% is the percentage that the patient achieved of the predicted work performance (192W) .

Following formula is used to calculate the predicted maximum work performance (maxWNorm):

maxWNorm (Men) = 6.773 + (136.141 x BSA) - (0.064 x A) - (0.916 x BSA x A)

maxWNorm (Women) = 3.933 + (86.641 x BSA) - (0.015 x A) - (0.346 x BSA x A)

BSA refers to the body surface area of the patient (according to DuBois) and is calculated as follows:

$(BSA) = H^{0.725} \times W^{0,425} \times 0.007184$

Legend: A = Age H = Height in cm; W = Weight in kg

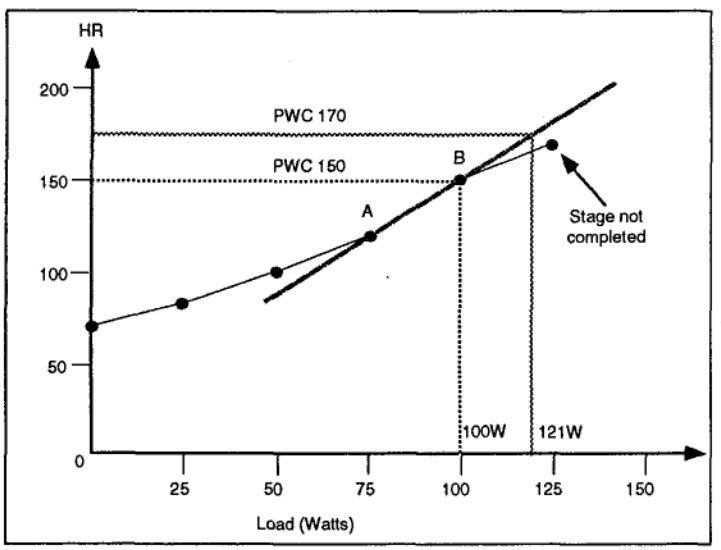
PWC 150/170

- The physical working capacity of the patient for a heart rate of 150/min and 170/min.

Assuming that there is a linear relationship between work load and heart rate, those values may be calculated based on the measured heart rate at the end of the last load stage and the measured heart rate at the end of the previous load stage (load stages which have been interrupted before the programmed time has elapsed will not be considered).

PWC 150/170 is given in Watts and can only be calculated when there is an increase in heart rate between the last two load steps of the test. Otherwise the value is not indicated.

The PWC 150/170 values are determined by the last two stages which the patient has *fully completed*. The two points A and B given by these stages (see Fig. 1 on next page) are connected by a straight line. The PWC values are given where this line crosses the projected 150/170 heart rate. This means that if a patient exceeds a heart rate of 170 the software still determines the PWC in the same manner. This can cause some slight deviation from the absolute PWC values but these are not relevant for a correct diagnosis.



PWC rel.

- The values of PWC 150/170 are divided by the weight of the patient giving an indication of the physical capacity related to the patient's body mass.

The normal values for the relative PWC 170 are:

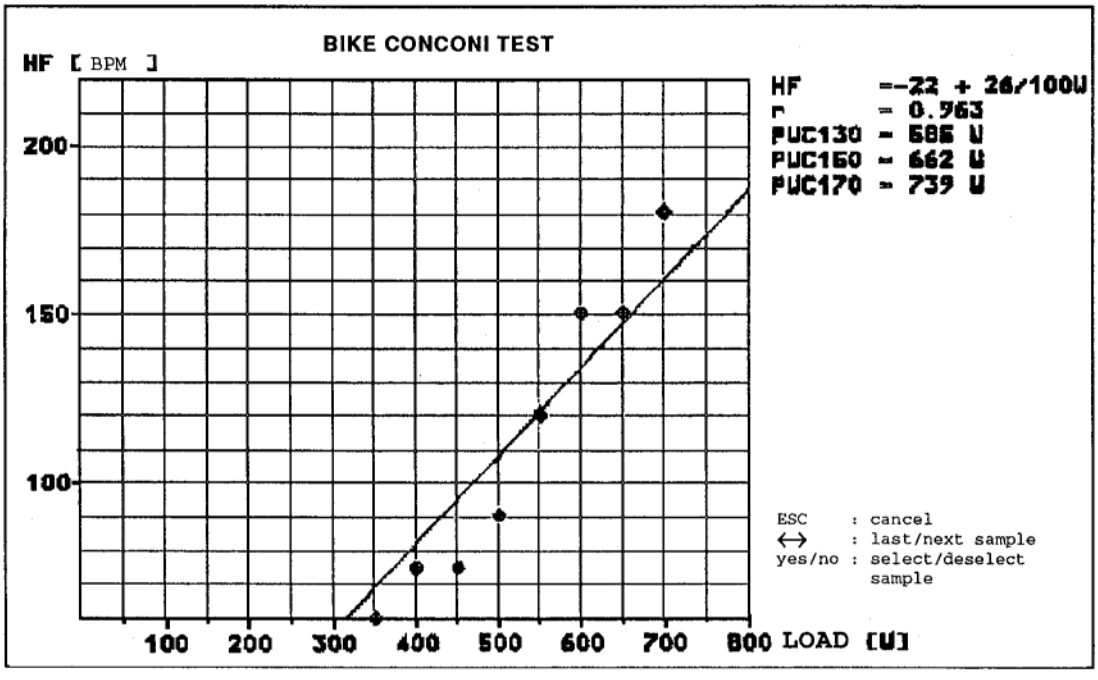
- Males: 3 W/kg (±0.5 W/kg)
- Females: 2.4 W/kg (±0.5 W/kg)

FINAL REPORT

Heart Rate/Load Diagram for Conconi Test

When you opt for the Conconi protocol for your bicycle test, a graphical representation of the relationship between heart rate and load will be provided at the end of the test. This diagram is displayed on the screen while printing the final report. It can be edited by activating or deacting reference points. Press the direction keys ▷ or ◁ to move to the next or to the previous reference point on the graph. Press the keys YES + or NO − to activate or deactivate the reference point selected. The position of the line on the graph will change accordingly.

Printout example:



Measurement results are provided in form of reference points. The approximation method is applied to obtain the best fitting line through the points. The result is a straight line in the graph. On the right-side of the screen, following values are given:

HF	=	mathematical formula for the absolute perfect line The indication ' HF: -22 + 26/100W' in the printout example signifies following: The first value gives the starting point of the line; when extending the line further down it will cross the vertical axis (heart rate) at this point. The second value gives the proportion of line slope relative to the factor of 100 W.
r	=	correlation coefficient = factor for the optimal fitting of the line based on the effective measurement results.
PWC 130	=	Watt performance at a heart rate of 130
PWC 150	=	Watt performance at a heart rate of 150
PWC 170	=	Watt performance at a heart rate of 170

The graph can be printed as displayed by pressing the key PRINT SCREEN.

NOTE: The diagram can again be displayed on screen and edited when entering the protocol menu (PROTOCOL -6).

FINAL REPORT

Final Report for Treadmill

All information resulting from a test with a treadmill is documented on the final report as follows:

- Trend plots of blood pressure, speed/elevation and heart rate
- Test data including:
  - Protocol identification
  - Start of recovery (time from the beginning of the exercise phase until the beginning of the recovery phase
  - End of stress test (total duration of test from start of exercise phase)
  - Max heart rate (maximum heart rate achieved and percentage that this rate is of the maximum calculated heart rate)
  - Max METS (maximum METS achieved)
  - Max BP (highest systolic and lowest diastolic pressure achieved)
  - Max BP (syst)* HR (this figure is derived by multiplying the highest heart rate achieved by the systolic blood pressure at that time)
  - Criteria for interruption (maximum number of 3)
- Patient data
- Date and time

The final report may include other information not listed above. Options are selected in the menu EXERCISE -3-3.

Separate Printout of Rhythm Lead R1

Upon completion of the final report you can initiate the separate rhythm printout.

Press the PRINT RHYTHM key to obtain the rhythm printout.

QUIT EXERCISE MODE

NOTE: *Before quitting the exercise test mode and switching off the unit, it is advisable to store the current settings for future use.*

To exit the exercise test mode at any time during the course of a test or after printout of the final report proceed as follows:

- Press
  - key **1** to remain in EXERCISE mode.
  - key **2** to quit and return to resting ECG mode.

NOTE: *The EXERCISE mode can also be quit by pressing the* 2ND *key followed by* ECG .

CHAPTER 5

Data Storage and Transmission

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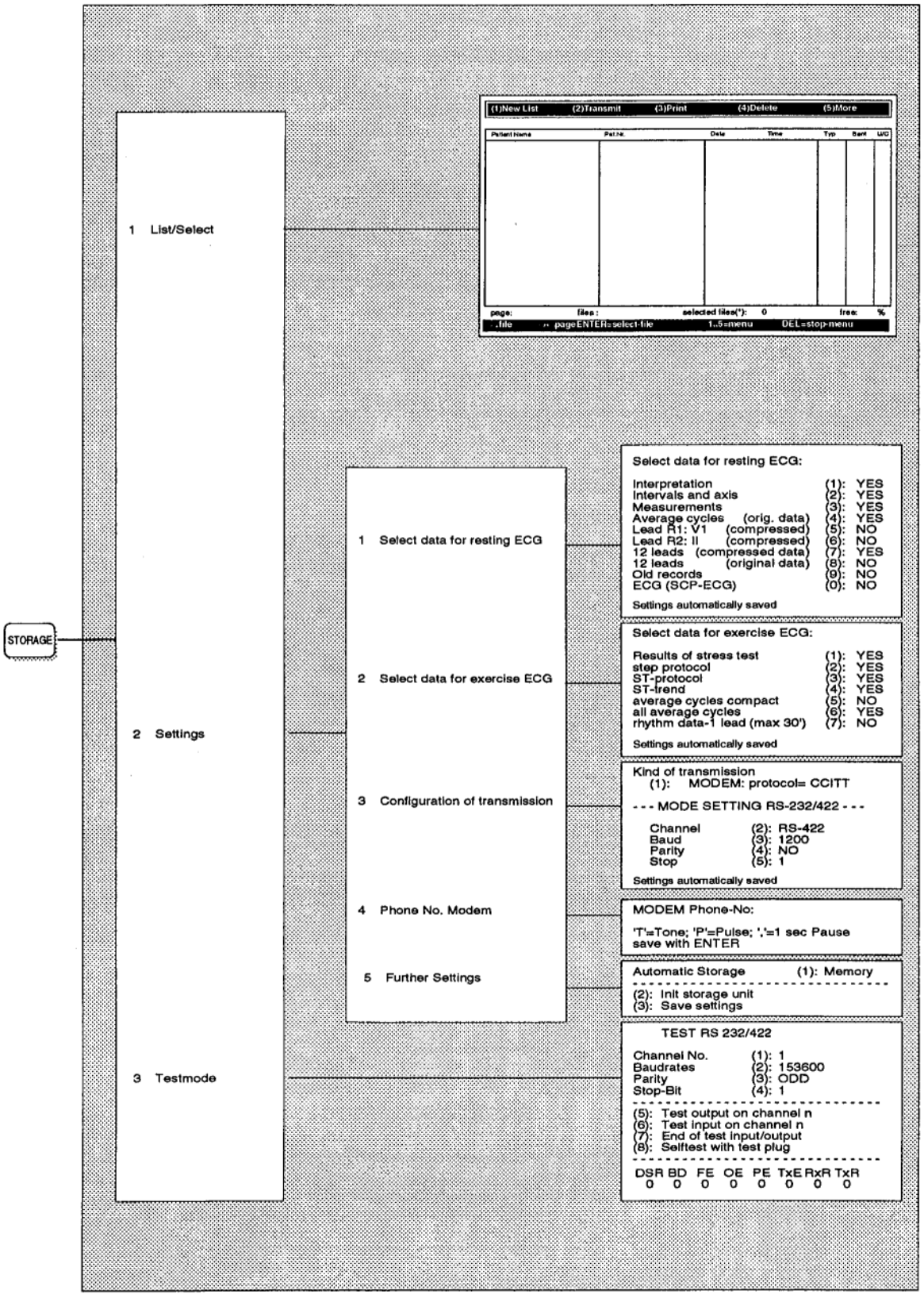
STORAGE MENU OVERVIEW

MEMORY Menu


STORAGE
1 List/Select
2 Settings
3 Testmode
(1)New List (2)Transmit (3)Print (4)Delete (5)More
Patient Name Pat.Nr. Date Time Typ Sent I/O
page: files: selected files(*): 0 free: %
..file .. pageENTER=select-file 1..5=menu DEL=stop-menu
1 Select data for resting ECG
2 Select data for exercise ECG
3 Configuration of transmission
4 Phone No. Modem
5 Further Settings
Select data for resting ECG:
Interpretation (1): YES
Intervals and axis (2): YES
Measurements (3): YES
Average cycles (orig. data) (4): YES
Lead R1: V1 (compressed) (5): NO
Lead R2: II (compressed) (6): NO
12 leads (compressed data) (7): YES
12 leads (original data) (8): NO
Old records (9): NO
ECG (SCP-ECG) (0): NO
Settings automatically saved
Select data for exercise ECG:
Results of stress test (1): YES
step protocol (2): YES
ST-protocol (3): YES
ST-trend (4): YES
average cycles compact (5): NO
all average cycles (6): YES
rhythm data-1 lead (max 30') (7): NO
Settings automatically saved
Kind of transmission
(1): MODEM: protocol= CCITT
--- MODE SETTING RS-232/422 ---
Channel (2): RS-422
Baud (3): 1200
Parity (4): NO
Stop (5): 1
Settings automatically saved
MODEM Phone-No:
'T'=Tone; 'P'=Pulse; ','=1 sec Pause
save with ENTER
Automatic Storage (1): Memory
(2): Init storage unit
(3): Save settings
TEST RS 232/422
Channel No. (1): 1
Baudrates (2): 153600
Parity (3): ODD
Stop-Bit (4): 1
(5): Test output on channel n
(6): Test input on channel n
(7): End of test input/output
(8): Selftest with test plug
DSR BD FE OE PE TxE RxR TxR
0 0 0 0 0 0 0 0

SETTINGS FOR STORAGE AND TRANSMISSION

General Information

The standard AT-10 comes with a variety of build-in interfaces for transmission/reception of ECG data to/from other SCHILLER units or a PC with SEMA, SCHILLER's data management and archiving program for PC-based single and network users.

Storage facilities are provided via the unit's internal memory.

Storage and transfer functions are carried out via the Storage menu. Press the key MEMORY to open the menu. Following display appears:

Full details are given on the following pages.

SETTINGS FOR STORAGE AND TRANSMISSION

Select Data for Storage and Transmission

Resting ECG Data

If resting ECG data is to be transmitted or stored, select the menu as follows:

MEMORY
< Settings >
Select data for resting ECG
Select data for resting ECG:
Interpretation (1): YES
Intervals and axis (2): YES
Measurements (3): YES
Average cycles (orig. data) (4): YES
Lead R1: V1 (compressed) (5): NO
Lead R2: II (compressed) (6): NO
12 leads (compressed data) (7): YES
12 leads (original data) (8): NO
Old records (9): NO
ECG (SCP-ECG) (0): NO
Settings automatically saved

With the keys **1 ... 9** and **0** select the data that you wish to transmit/store. The options are YES to select or NO to suppress.

-> Selections 5 and 6 are the programmed rhythm leads R1 and R2.

NOTES: *When one of the selections 1 to 7 is set to YES, positions 8, 9 and 0 are automatically set to NO.*

When selection 8 '12 leads (original data)' or 9 'Old records' is set to YES, all other positions are automatically set to NO.

"ECG (SCP-ECG)" stands for standard communication protocol. This protocol is used for data communication between electrocardiographs and PC-based data management systems or other SCHILLER ECG systems where data can be stored. In order to communicate, however, both units must support this protocol type. When this option is set to YES, postions 1 and 3 are automatically set to YES.

This protocol can also be used for storing data in the unit's internal memory. It permits to store more ECGs in the memory than with any other selection.

Exercise ECG Data

If exercise ECG data is to be transmitted, select the menu as follows:

MEMORY
< Settings >
< Select data for exercise ECG >
Select data for exercise ECG:
Results of stress test (1): YES
step protocol (2): YES
ST-protocol (3): YES
ST-trend (4): YES
average cycles compact (5): NO
all average cycles (6): YES
rhythm data-1 lead (max 30') (7): NO
Settings automatically saved

With the keys **1 ... 7** select the data that you wish to transmit. The options are YES to select or NO to suppress.

NOTE: *Selection 7 'rhythm data - 1 lead (max. 30')' is the programmed rhythm lead R1.*

NOTE: *Exercise ECG data can only be transmitted manually and with the EXEC option installed (EXEC is SCHILLER's analysis program for exercise ECGs). Before transmitting the selected data, the final report must be printed out and the automatic function must be disabled.*

Exercise ECGs cannot be stored in the memory.

All settings made will automatically be saved.

SETTINGS FOR TRANSMISSION

Setup Unit for Transmission

Call up the menu for settings as follows:

Select Line or Modem Transmission

- Key **1** selects **line** or **modem** transmission and the format and protocol for the selected mode.

Line Transmission:

- Select between
  - Format = RECORDS
  - Format = BLOCKS
- Record transmission is quicker and simpler. Block transmission is more secure as the transmitted data is checked for errors and corrected accordingly.

NOTE: *For the data transfer to SEMA only use BLOCKS.*

Modem Transmission:

- Select between
  - Protocol = CCITT
  - Protocol = BELL

Set Communication Parameters

- Key **2** selects the **channel,** i.e. the RS connector at the rear of the unit used for the connection
  (Select RS-232 or RS-422)
- Key **3** selects the required **baud rate.**
  (The following values are available: 75, 150, 300, 600, 1200, 2400, 4800, 9600, 19200, 38400, 76800, 153600 Baud)
- Key **4** selects the **parity.**
  (The available choices are NO, EVEN, and ODD)
- The length of the **stop bit** is determined by pressing key **5.**
  (The available choices are 1, 1.5 and 2)

NOTE: *Ensure that the above settings are the same in both the transmitting and the receiving unit.*

All settings made will automatically be saved.

SETTINGS FOR TRANSMISSION

Enter Phone Number for Modem Transmission

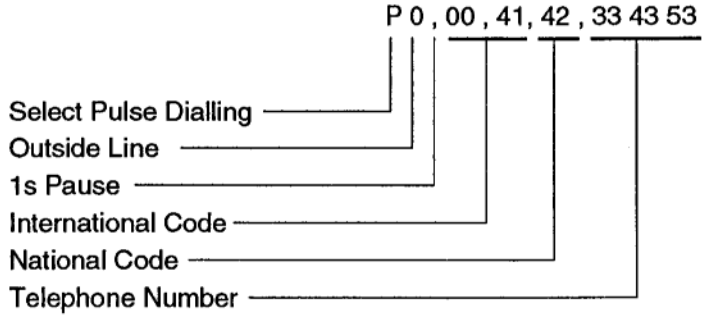
Call up the menu for entering the phone number as follows:

- Before entering the telephone number the type of dialling must be entered (**T** for tone or **P** for pulse). This is determined by the type of telephone exchange. All modern exchange now use tone dialling; older exchanges use pulse dialling. If in doubt select pulse.

NOTE: *If it is necessary to enter a pause in the dialling sequence, then enter a comma. The comma gives a one second pause, if a longer pause is required, two or more commas can be entered. This may be required for example, if you have to wait for an outside line. To give the exchange time to set up the connection, it is also a good idea to insert a pause after a national or international code.*

- Enter the telephone number (maximum number of characters is 17). (In view of different requirements, the symbols * and # are also accepted for the entry.)
- Save the entry by pressing **ENTER**.

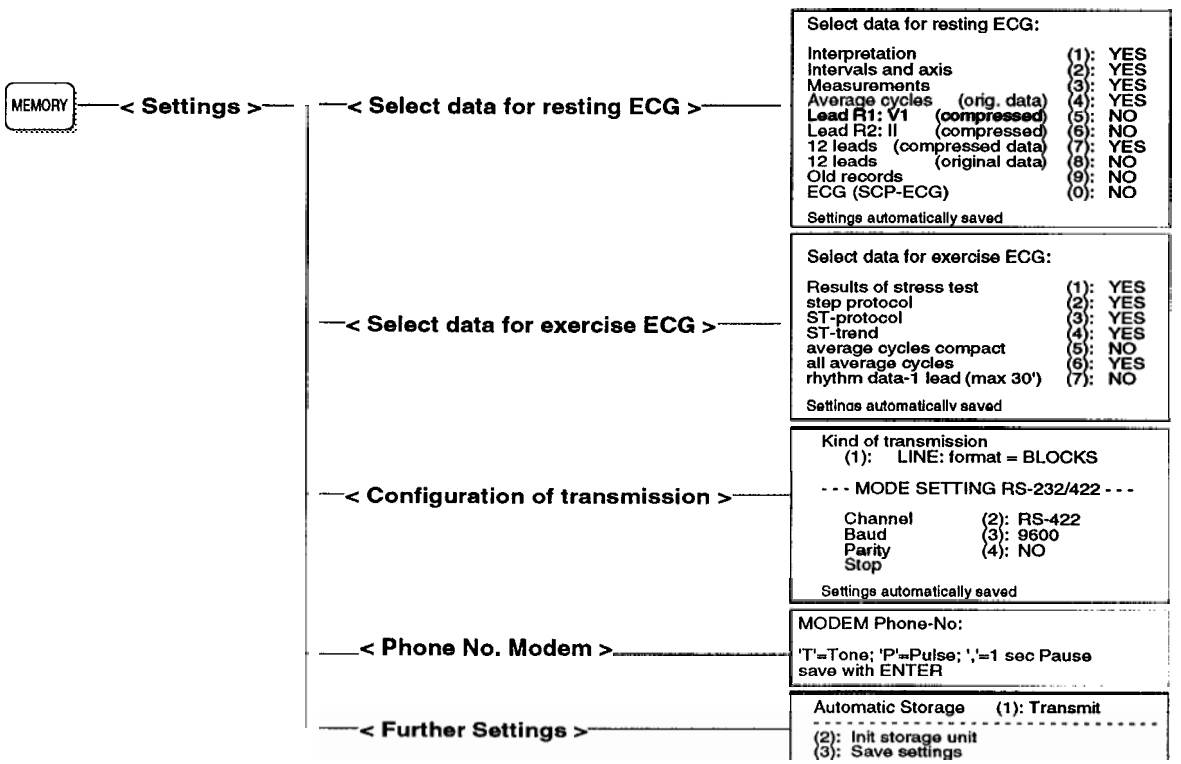
A typical example for the entry could be as follows:



SETTINGS FOR TRANSMISSION

Setup for SEMA

A typical setup if the data should be transmitted to SEMA (SCHILLER Data Management System) could be as follows:



DATA TRANSMISSION

Automatic Transmission

NOTE: *For resting ECGs only.*

If the recorded data of a resting ECG should to be stored or transmitted automatically, set the parameters as follows:

With key **1** the following options can be selected:

NO Data is not stored or transmitted.

Transmit Data is transmitted automatically to the connected unit (as previously defined).

Memory Data is stored directly into the unit's internal memory.

Key **2** will initialize the storage medium .

Key **3** saves the settings made.

Manual Transmission

- Ensure that automatic storage or transmission is not enabled (MEMORY -2-5-1-NO).
- To manually transmit an ECG, simply press the SEND DATA key after the recording is finished.

The message "CONNECTING" appears in the status field in the upper right of the screen followed by "TRANSMITTING". During transmission, numbers from 1 to 9 appear successively in the status filed to indicate the progress of the transmission. Once the transmission is completed, there is an audible signal and the message "ECG IS OUTPUT" is given in the status field.

NOTE: *Only the ECG which is currently in the working memory can be transmitted. If no ECG is in the memory when the TX DATA key is pressed, an audible alarm will sound and the message "NO ECG IN MEMORY!" will appear in the status field.*

RECEIVING AN ECG FROM ANOTHER DEVICE

Setting up the Unit for Data Reception

To receive data from another device proceed as follows:

The AT-10 must be set up to match the parameters of the sending unit as described for data transmission.

CAUTION!

INCOMING DATA WILL OVERWRITE ANY DATA WHICH IS CURRENTLY IN THE WORKING MEMORY.

- Press the RECEIVE DATA key. The AT-10 is now in the receive mode and waits for incoming data from the transmitting unit (the message "WAITING FOR DATA" appears in the status field).
- Start data transmission at the transmitting unit.
- When the incoming data is received, press the RECEIVE DATA key once again to quit the receive mode.

  The following message appears on the display:

  (1): Quit RECEIVE MODE
  (2): Continue RECEIVE MODE

- Press key 1 to quit.

When the data is received, a printout of the ECG in format 1 is initiated. The received ECG is now in the internal working memory and remains there until it is overwritten.

Store Incoming Data

To store the data received in the unit's internal memory, proceed as follows:

- Press STORE DATA.

DATA STORAGE

The AT-10 contains a memory to store approximately 40 ECGs depending on the data selected. Archiving can be carried out either automatically or manually. Only resting ECG recordings taken in Auto Mode can be stored. For fast and easy retrieval, all stored data are presented in a list format (see "Data Management" later in this chapter).

NOTE: *It is also possible to store Late Potential and Heart Rate Variability recordings if the appropriate options are installed in your unit.*
Exercise ECGs, however, cannot be stored.

Automatic Storage

- Press MEMORY - 2 -5 and set Automatic Storage to "Memory" with key **1:**

(for further details see page 5.8).

- Select the data to be stored (see "Select Data for Storage and Transmission").
- Take an ECG recording in auto mode (AUTO START key) - archiving follows automatically after the ECG evaluation.

Manual Storage

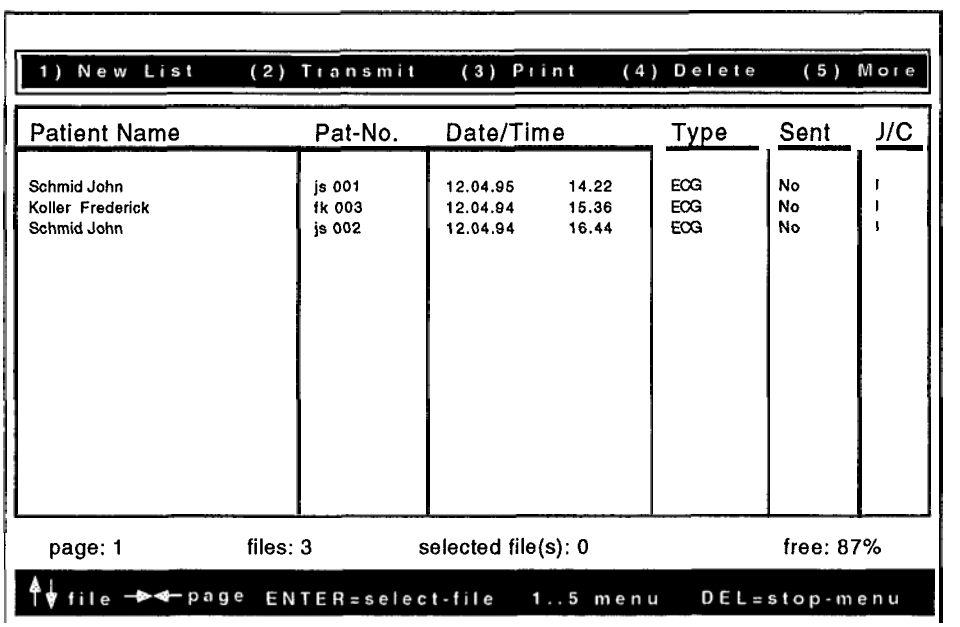
Once an ECG has been taken and the data to be stored selected, press the STORE DATA key to store the data.

The message "WRITING DATA" is displayed (for manual and automatic storage). Once storage is completed, there is an audible sound and the message "DATA WRITTEN" is given on the display.

DATA MANAGEMENT

The AT-10 automatically maintains a list of all data stored in the unit's internal memory which allows you to recall the data later as needed for printing or transmission. Files are identified by the patient's name and ID number plus the date and time that the data was recorded.

Press the MEMORY key followed by key 1 (List/Select) to display the list of stored data. A display similar to the following will appear on the screen.



The **top line** gives the following main menu options . To select a menu use the direct number keys. These main menu functions lead to more selection possibilities. To execute a function, press the ENTER key.

(1) New List — updates the list of data currently stored in the memory, reverts to page 1 of the list.

(2) Transmit — transfers all or selected file(s) to another unit or PC (e.g. SEMA program). Remaining files are those files which have not yet been transfered. For files transmitted , the indication "Yes" will appear in the column "Sent".
- Transmit file(s)
- Transmit all files
- Transmit remaining files

(3) Print — prints all or only selected file(s) using print format 1
- Print file(s)
- Print all files

(4) Delete — deletes all or selected file(s) in the list/memory. "Delete sent files" will erase all files sent to another unit. *When deleting files, you must confirm that you wish to delete.*
- Delete file(s)
- Delete all files
- Delete sent files

(5) More — prints a list of all files
- Print file dircectory

DATA MANAGEMENT

The **middle section** of the list displays the files currently stored in the memory. 20 files can be displayed on one page. To see more, use the arrow right/left keys.

For each file following information is given:
- patient name
- patient number
- date and time of recording
- recording type, e.g. ECG (or POT =Late Potential, VRR = HR Variability)
- transmission status, i.e. files transmitted or not
- Unconfirmed/confirmed report (U= Unconfirmed, C= Confirmed)

To select a file , use the arrow up/down keys and press the ENTER key. The file selected will be marked with an asterisk (*).

In the **bottom lines** following is given:
- number of files currently displayed
- total number of files stored
- number of files selected
- the remaining storage capacity

- help function for file/menu selection

ERROR MESSAGES

General Messages	
NO ECG DATA AVAILABLE	No ECG has been recorded.
NO PATIENT DATA	No patient data is entered (enter at least one letter for the patient's name).
Data Transmission	
NO ECG IN MEMORY!	An ECG transmission has been attempted, but no ECG is stored in the unit's memory (the ECG has not been recorded in auto mode).
LINK TIME-OUT!	This indication appears if no signal is received from the remote unit (for example when the connecting cable is not correctly plugged in).
DATA SET NOT READY	The ECG data cannot be transmitted because the receiving unit is not ready for operation.
DATA NOT VALID !	No meaningful data received.
ARCH. FLAG ERROR! ! !	This message appears when an ECG transmission has been attempted but could not be completed successfully.
Data Storage	
DATA NOT VALID	Data cannot be stored.
SELECT DATA FOR ARCH.	The data to be stored has not been selected.
MEMORY FULL	Memory is full, new data cannot be stored (delete records no longer needed).

CHAPTER 6

Recording External Signals via the DC Inputs

Recording External Signals 6.3
Using the DC Inputs 6.3
Signal Acquisition 6.3
Displaying and Printing the Signals 6.4

RECORDING EXTERNAL SIGNALS

Using the DC Inputs

The DC inputs enable the signals from an external unit to be displayed on the AT-10 screen and to be printed out via the unit's printer. This can be done alone or in conjunction with an ECG recording.

An example of an external device which could be connected, is a phonopulse recording unit or a small ECG unit (i.e. MS-3).

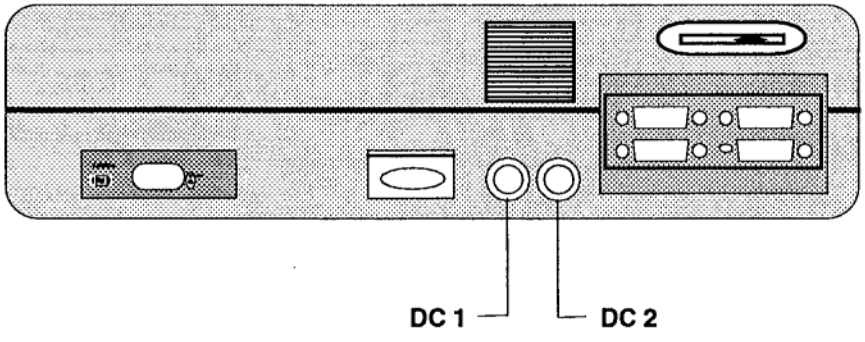
Signal Acquisition

For the signal acquisition following preparations are necessary:

- Connect the external unit to the DC input socket.
- Set the programmable leads to reflect the DC input used.
- Select monitor channels and lead group for display.
- Select printer channels and lead group for printout.

Connect External Unit

Insert the plug of the connecting cable from the external unit into one of the two DC input sockets located on the right-hand side of the AT-10.

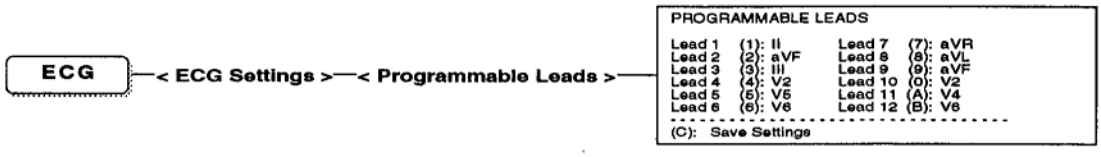


RECORDING EXTERNAL SIGNALS

Signal Acquisition (Cont.)

Select DC Leads

The leads required have first to be programmed for the desired channels. To do this, the menu for the user-programmable leads has to be selected as follows:



Press the number or letter key indicated in parenthesis to select the lead position where the current lead is to be replaced by the DC lead.

Press the NO – or YES + keys until the required DC lead (DC1, DC2) appears.

Selectable Leads

The following leads are selectable:

I	II	III	aVR	aVL	aVF	V1	V2	V3	V4	
V5	V6	-aVR	**DC1**	**DC2**	V7	V8	V9	D	A	J

NOTE: *To display the new lead sequence on the screen (or select it for the manual printing) press the lead keys LEAD ◁ or LEAD ▷ until the selected leads appear.*

Displaying and Printing the Signals

Display and printout settings are the same as for resting ECGs (see Chapter 3).

CHAPTER 7

Maintenance, Tests and Troubleshooting

Maintenance **7.3**
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Cleaning your AT-10 ..... 7.4
Cleaning the Patient Cable 7.4
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Technical Safety Check 7.5
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Electrical Interferences 7.7
Restarting the Unit (Master Reset) 7.7
Operating Problems During Data Transmission 7.7
Fault Diagnosis **7.8**

MAINTENANCE

Replacing the Recording Paper

A red strip on the bottom edge of the recording paper indicates that it needs to be replaced. When this strip appears, there are about eight pages left. We recommend that the paper be replaced as soon as this indication appears. Should the paper run out completely, then an audible alarm is initiated and the message "REFILL PAPER!" appears on the display. To replace the paper, proceed as follows:

- Press the key REPLACE PAPER. The paper tray slides out automatically.
- Remove any remaining paper from the paper compartment.
- Take a new pack of recording paper and place it into the paper compartment with the grid side upper most and the black paper mark at the top.
- Pull the first sheet out of the paper tray to that it is over the roller.
- Press the REPLACE PAPER again. The paper tray slides back automatically.
- Press the STOP key, and the paper is transported to the correct starting position. When printing is restarted, the warning message will be removed from the display.

NOTE: *WELCH ALLYN can only guarantee perfect printing quality if the original chart paper or paper of equal quality is used.*

MAINTENANCE

Cleaning your AT-10

The casing of the SCHILLER AT-10 can be cleaned with a soft cloth on the surface only. **Switch the unit off before cleaning and disconnect from mains supply.**

NOTE: *Do not, under any circumstance, immerse the apparatus into a cleaning liquid or sterilize with hot water, steam, or air. Do not clean the keyboard with benzine, nitrobenzene or acetone!*

Cleaning the Patient Cable

The **patient cable** should not be exposed to excessive mechanical stress. Whenever disconnecting the leads, hold the plugs and not the cables. Store the leads in such a way as to prevent anyone stumbling over them or any damage caused by the wheels of instrument trolleys. The cable can be wiped with soapy water. Sterilization, if required, should be done with gas only and not with steam. To disinfect, wipe the cable with any standard hospital disinfectant.

The **electrodes** can be cleaned after every use with soapy water. Make sure that no water is left in the suction cup of the suction electrodes. Sterilization can also be performed with gas or with Alhydex or Vygon.

Check Mains Voltage

Your AT-10 can be set to operate at nominal line voltage ranging from 100 to 240 Volts. The voltage is usually set at the factory to the setting for your area. **Before connecting the AT-10 to the mains supply, check the voltage power setting on the fuse box located at the rear of the unit.**

If the voltage setting is incorrect, change it to the correct setting, as given in the following table:

Local Mains Voltage (V)	Unit Settings (V)
100 / 110 / 115	110
120 / 127	120
200 / 220 / 230	220
240	240

To change the Mains Voltage setting, proceed as follows:

- **Remove the fuse box by inserting the tip of a small screw** driver into the recess next to the fuse box.
- Insert the tip of the screw driver between the black overlapping part (marked with an arrow) and the green part of the voltage selector until this latter part is released and can be taken out.
- The four possible voltage selections are marked on the voltage selector. Turn the voltage selector with the required voltage into the direction of the arrow and slide it into the fuse box until it clicks.
- Slide the fuse box back into the opening on the rear panel of the unit until it clicks.

MAINTENANCE

Technical Safety Check

Terms

At 12 monthly intervals, the unit should undergo a technical safety check.

Extent

The extent of this check should include the following:

- Visual inspection of the unit and cables.
- Electrical safety tests according to IEC 601-1 and IEC 601-2-25.
- Functional tests according to the Service Handbook.

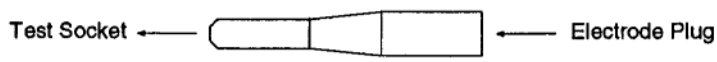
The test results must be documented.

TESTS

Checking the Patient Cable

The electrode leads can be tested for short-circuit and interruption by means of the test socket located on the side panel of the unit.

- Use the special coupling that is delivered as accessory with the unit and connect with the electrode plug.



- Ensure that the AT-10 is switched on and the patient cable plugged in. Now insert the electrode plug into the test socket.

The test indicator should light indicating that the lead is satisfactory. Repeat the test for all leads.

Testing the Transmission Channels

To check the integrity of the transmission channels and the cable assemblies between the two communicating units, a transmission/reception test option is available for the AT-10. These test options are intended for authorised service personnel only. Full details are given in the relevant service handbook.

Viewing the menu settings

A list of all menu settings can be displayed on the screen. This is only possible, however, when the screen is clear, i.e. no menu or data entry fields displayed. Press key **M** to display the list. You may also obtain a printout by pressing the key PRINT SCREEN.

Note: At the time of print, this function was not fully defined.

TROUBLESHOOTING

Electrical Interferences

Thanks to digital transmission of the ECG signals the influences of electrical interferences and artefacts are reduced to a minimum.

Disturbances in the mains supply are suppressed by a mains filter (adaptive digital filter) without influencing the ECG signals.

To avoid electrical interferences, ensure when using the unit that it is set up in proper distance to any interference sources (such as electrotherapy units, X-ray appliances, strong lamps or current conductors).

Restarting the Unit (Master Reset)

In exceptional circumstances the unit can 'lockup'. None of the keys respond and the screen is blocked. When this happens, the reset button must be used to restart the unit.

The reset button is located on the lower left-hand side of the unit, underneath the paper tray and is accessible through a recess.

For restarting, insert the tip of a pencil into this recess to press the reset button.

CAUTION!

ALL STORED DATA IS LOST WHEN PRESSING THE RESET KEY.

Operating Problems During Data Transmission

When communication between the transmitting and the receiving unit is interrupted, it may no longer be possible to access the list of stored data with the function "List/Select". In this case, the storage medium must be initalized.

Proceed as follows:

- Enter the following menu:

- Press key **2** to initialize the storage medium .

FAULT DIAGNOSIS

Blank Screen

- Green mains indicator on?
  - No? Check mains supply.
  - Yes? Check the screen contrast.
- If mains is OK and the screen is still not lit:
  - Press the master reset button on the side of the unit with a pointed instrument.
  - Wait a few seconds and switch on again.
- If the screen is still not lit:
  - Call your local WELCH ALLYN representative.

QRS traces overlap

- What to do?
  - Ensure that the automatic sensitivity reduction is not switched off.
  - Reset signals to baseline (press key).
  - Check electrode contact.

'Noisy' traces

- What to do?
  - Check electrode contact.
  - Reapply electrodes.
  - Ensure that the patient is relaxed and warm.
  - Check all filter settings.
  - Activate myogram filter (press

key).
  - Ensure mains filter is correct for mains supply.

No printout obtained after an auto mode recording

- What to do?
  - Ensure that 'Number of Copies' is not set to '0'.
  - Ensure that at least one format option is selected, e.g. an ECG lead option.
  - Ensure that paper is loaded.
- Does the printer still not function after having pressed the

key?
  - Contact your local WELCH ALLYN representative.

FAULT DIAGNOSIS

Printout fades or is not clear

- What to do?
  - Ensure that fresh WELCH ALLYN SCHILLER paper is installed.
  - Note that the thermal paper used for the AT-10 is heat and light sensitive. If is not stored in its original seal, stored in high temperatures or is simply old, print quality can deteriorate.
  - Ensure that the paper has been installed correctly with the paper mark at the top.
  - Ensure that paper is loaded.
- If the problem persists call your local WELCH ALLYN representative.

No printout of interpretations statement or measurements

- What to do?
  - Check that the interpretation and measurement options are enabled for the printout.
  - Check that the format selection allows printing the measurement table and the interpretation statements.

No key response, LCD locked

- What to do?
  - Press the master reset button.

CHAPTER 8

Technical Data

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TECHNICAL DATA AT-10

NOTE: *Technical data are subject to change without notice*

Unit, Monitor, Keyboard

Dimensions: 320 x 264 x 70 mm (l/w/h)
12.6 x 10.5 x 3.0 in

Weight: approx. 4.7 kg (10 lbs)

Power supply requirements (mains):
100 to 240 Vac, 50 / 60 Hz

Fuses: for 230/240 V: 2 x 200 mAT
for 110/120V: 2 x 400 mAT

Battery: rechargable NiCad-battery (2 x 12 V, 0.8 Ah)
recharging time: approx. 15 h (100%),
approx. 3 h (80%)
continuous operation (without printing):
approx. 1 h

Line frequency filter: distortion-free suppression of superimposed 50 or 60Hz sinusoidal interferences by means of adaptive digital filtering

Power consumption: 13 to 30 VA

Liquid crystal display: backlit liquid crystal display for graphic and alphanumeric representation
Resolution: 640 x 480 pixels;
viewing angle adjustable
Dimensions: 196 x 148 mm
(245 mm diagonal)

Paper speed: 2.5 / 5 / 10 / 12.5 / 25 / 50 / 100 mm/s

Control panel and keyboard:
water and dustproof keypad

Environmental conditions:
temperature, operating: 10° to 40 °C
temperature, storage: 0° to 50°C
relative humidity: 25 to 95%
(non-condensing)

Printer

Printing process: high-resolution thermal printhead
200 dots/in or 8 dots/mm (amplitude axis)
0.3 mm/pixel ~ 3^1/2 dots per mm or 89 dots per in (time axis) @25 mm/s

Chart paper: thermoreactive, Z-folded,
length approx. 35 m, width 21 cm (8.5),
performation each 14 cm (11 in)

TECHNICAL DATA AT-10

ECG Signal Inputs

Frequency range of digital recorder:
0 to 150 Hz (IEC/AHA)

Patient input: fully floating and isolated, defibrillation protected

Patient leakage current: less than 5 µA

Safety standard: CF according to IEC 601-1 and IEC 601-2-25

Protection class: I according to IEC, VDE and SEV

Standard Interfaces

Serial interfaces: 3 x RS-232 (V24)
1 x RS-422

Video connection

QRS trigger / Foot switch connection

Stress test interface

DC Inputs 0.5 V/cm

ECG Registration

Leads: up to 12 simultaneous leads: Standard / Cabrera / Nehb, V7, V8, V9
further combinations programmable by user

Automatic lead programs:
3 or 6 channel representation on one or two forms size A4 (8.5 in by 11 in)
(25, 50 or 100 mm/s)
with options M and i:
average complexes of the 12 standard leads (25 or 50 mm/s)
10 s rhythm strip (1 or 3 leads)

Data record: Listing of ECG recording data, date and time of recording, patient data, etc.
Options M and i:
ECG measurement results (intervals, amplitudes, electrical axes), average complexes with optional measurement reference markings
Option C:
ECG interpretation statements

Long-term rhythm recording:
1 lead
90 s/page or 5, 10 min/page

TECHNICAL DATA AT-10

ECG Registration (Cont.)

Exercise ECGs with final report:
automatic control of bicycle ergometer and treadmill (user programmable)
Final report showing trendplots of heart rate, load (or speed and elevation) and blood pressure, physical working capacity (PWC 150, PWC 170, PWC max.)
Options M and C:
QRS and ST measurements

Myogram (muscle tremor) filter:
adjustable at 25 or 35 Hz, only effective on printed ECG

Sensitivity: 2.5 / 5 / 10 / 20 mm/mV, either automatically adjusted or manually selected

Recording tracks: 3, 6 or x channels selectable (x = freely selectable between 4, 5 or 7), positioned at optimal width on 200 mm (8.5 in), automatic baseline adjustment

ECG amplifier: simultaneous, synchronous recording of all 9 active electrode signals (= 12 leads)

sampling frequency:	4 kHz
digital resolution:	2.5 µV (min)
dynamic range:	±16 mV
max. electrode potential:	±300 mV
frequency response:	0 to 350 Hz (-3 dB)
common mode rejection:	>100 dB / 50 or 60 Hz
input impedance:	>100 MΩ

pacemaker detection / measurement:
measurement voltage range ±1 to ±500 mV
measurement duration range 0.1 to 5 ms

(Technical Data to change without notice)

INPUT/OUTPUT CONNECTIONS

Exercise Test Interface

Input impedance:	>100 kΩ	Pin 1	RPM Input: 100 RPM/V
Output impedance:	>100 kΩ	Pin 2	GND
		Pin 4	Load input: 100 W/V
		Pin 5	Load output: 100 W/V

DATA I/O Connector

TTL logic level: 5 VDC

Max. non-destructive voltage:
+15 VDC, or -10 VDC (2.5 kV static discharge)

Pin 1 =	QRS-Trigger	(50, 100, 150, 200 ms)
Pin 2 =	GND	
Pin 3 =	footswitch	(contact to GND = START)
Pin 4 =	TM DN	
Pin 5 =	TM UP	

Video Connector

D sub, 15 pole, High-density, female

Pin 2 =	Video
Pin 5 =	Test
Pin 7 =	Video GND
Pin 9 =	D CLK
Pin 10 =	Sync GND
Pin 11 =	DISP
Pin 13 =	H-SYNC
Pin 14 =	V-SYNC

Resolution:	640 x 480 pixels	
Input signals:	horizontal sync.:	TTL (positive)
	vertical sync.:	TTL (negative)
	video:	0 to 0.7V
Scanning frequency:	horizontal:	31.3 kHz
	vertical:	60 Hz

INPUT/OUTPUT CONNECTIONS

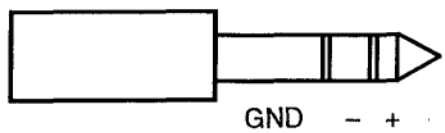
DC Inputs

Specification differential inputs

Sensitivity: 0.5 V/cm

Input impedance: > 100 kΩ

Maximum continuous voltage: 150 V (short-term 220 V)



SERIAL INTERFACES

RS-232 Interfaces (V24)

Protocol:	asynchronous
Baud rate:	75 to 153600 Baud
Byte format:	1 start bit, 8 data bits 0 or 1 parity bit (+ or -), programmable 1 / 1,5 / 2 stop bits, programmable
Transfer control:	by means of DTR, DSR, CTS, RTS
Connection socket:	3 x D subminiature (9 pole female), wired as DTE (Data Terminal Equipment)

Pin connections, channel 1,2,3:

3	=	TXD	O	=	(output data)
2	=	RXD	I	=	(input data)
7	=	RTS	0	=	(request for output)
8	=	CTS	1	=	(ready for output)
6	=	DSR	1	=	(receiving unit ready)
4	=	DTR	0	=	(transmitting unit ready)
5	=	GND (ground)			

RS-422 Interface

Protocol:	Asynchronous
Baud rate:	75 to153600 Baud
Byte format:	1 start bit, 8 data bits 0 or 1 parity bit (+ or -), programmable 1 / 1.5 / 2 stop bits, programmable
Transfer control:	TXC, RXC
Connection socket:	1 x D sub, 9 poles

Pin connection:

1	=	GND
2	=	TXC +
3	=	TXC -
4	=	RXC +
5	=	RXC -
6	=	RXD +
7	=	RXD -
8	=	TXD +
9	=	TXD -

ANNEX A

EXEX ANALYSIS PROGRAM FOR EXERCISE ECGS

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INTRODUCTION

EXEC is a special program for the real time recording and evaluation of all the data accumulated during exercise testing. With the help of established signal processing algorithms, EXEC carries out a complete analysis of the ECG (12 simultaneous leads).

Furthermore, specific parameters such as blood pressure and subjective symptoms are entered, coordinated according to time and finally integrated into the final report. Additionally, the EXEC program contains the facility for providing the physician with a diagnostic statement in relation to the probability of coronary artery disease (CAD).

The main objective of the EXEC program is to accomplish an accurate evaluation of exercise testing and to document all relevant information clearly and concisely.

CHAPTER 4

EXEX ANALYSIS PROGRAM FOR EXERCISE ECGS

PERFORMANCE OF THE EXEC PROGRAM

Determination of the Dominant QRS Cycle

EXEC localizes, measures and classifies each recorded ECG cycle. In order to have an efficient beat classification, precise knowledge of the "normal" QRS type is a prerequisite.

For this purpose, a *learning process* is necessary, which EXEC carries out immediately after starting an exercise test, i.e. during the "P" or pre-exercise phase. EXEC informs itself in the first place about the frequency of the occurring QRS patterns. The first five QRS are used for the learning process. From these five complexes a characteristic vector is acquired, which describes the dominant QRS type. This so-called reference vector now serves as a comparison vector for subsequent classification of all the accumulated ECG cycles.

As the shape of the QRS can change continuously during the exercise test, EXEC adapts the reference vector to the changes. When the QRS changes are abrupt (e.g. at an intermittent bundle branch block) a new learning process is automatically initiated. The duration of the learning process depends on the heart rate. As a rule it lasts for 8 to 12 seconds.

QRS Classification

After concluding the learning process, EXEC is in a position to process each ECG cycle immediately. With the help of artefact-insensitive measuring algorithms, EXEC determines a characteristic vector that specifies the QRS complex to be processed and which is structurally identical to the reference vector.

Both these characteristic vectors are then compared via a specific decision logic procedure. Through a suitable combination of the measurement results, taking into consideration the empirically determined tolerance range, EXEC classifies the measured QRS.

Each QRS is classified for signal processing and for medical criteria. The possible classes and the respective processing are shown in the following tables.

Signal Processing Classes

Class	Description	Processing
1.1	Dominant QRS type without strong distortion	Averaging / Update reference vector / Heart rate calculation
1.2	Dominant QRS type with strong distortion	Heart rate calculation / no averaging
1.3	Non-Dominant QRS type	Heart rate calculation / no averaging
1.4	Artefact	Heart rate calculation / no averaging

Medical Classes

Class	Description	Processing
2.1	Normal beat	Rhythm analysis
2.2	Supravenicular extrasystole	Rhythm analysis
2.3	Ventricular extrasystole	Rhythm analysis / VES typisation
2.4	Bundle branch block picture	Rhythm analysis

The classification from the signal processing view, is essential in determining whether or not a beat can be used for averaging. The classification according to the medical point of view determines which part the QRS complex has to play in the subsequent rhythm analysis.

Construction of the Representative Cycles (Averaging)

The aim of reducing the superfluous information and at the same time increasing the quality of the interpretation is achieved through the computation of representative ECG cycles. The representative cycle (standard cycle) always corresponds to the actual normal cycle.

For the formation of a genuine standard cycle free of artefacts, the established method of beat averaging is provided. This is an efficient method to dispose of artefacts, a method that uses the peculiarities of the ECG signals. On principle one utilizes the characteristics of the ECG as a redundant periodic process. The average complex formed by a multitude of normal beats full of artefacts thus leads to a good approximation of the artefact-free original signal.

EXEC uses an incremental-averaging-algorithm with baseline correction. This is a method which allows only the recurring parts of the signal to be fed into the result. The average cycle is always up-to-date and available at any time.

Analysis of the ST Segment

On the averaged cycle, the ST analysis occurs every 4 seconds. EXEC determines the position of the J point with the help of a pattern recognition process (template method). If the J point, in relation to the resting cycle, is higher by 0.1 mV, the system would then classify it as ST elevation. The analysis of the ST segment shape thus becomes superfluous. The same applies for the J amplitudes which differ between 0.1mV and -0.1mV. The ST segment is then classified as unobtrusive.

In the event that the J point differs more than -0.1mV, EXEC identifies an ST depression and carries out an analysis of the shapes of the ST segment in the first 80 milliseconds. It also determines whether the ST segment in this area is fairly rectilinear. Should this be the case, the slope of the regression line in the first 40 milliseconds serves as a measurement for classification.

The table below shows the ST classifications and their respective criteria:

NOTE: For the USA, the unit measurement 'mm' will be used instead of mV.

Rhythm Analysis

The aim of the rhythm analysis is to provide a qualitative and quantitative statement about the heart rhythm during the course of the test. The following rhythm disturbances are determined:

Ventricular Extrasystoles (VES)

In order to classify the VES, criteria such as duration and shape of the QRS are drawn upon. At the same time the RR distance has to be shortened.

VES-Types

Beats classified as VES are transferred to a typification algorithm. Up to 5 VES types are differentiated. A VES type is only recognized as such, when at least two matching QRS complexes are identified.

Frequency of VES

VES are counted and successive VES are identified as chains of two or three. At more than three successive VES, a ventricular tachycardia is determined.

Degree	Abbreviation	Class	J-amplitude D (mV)	ST shape	Slope (mV/sec)
0	–	unobtrusive	0.1 > J > 0.1		
1	AS	asending	J < -0.1	rectilinear	s > 1.0
2	SA	slowly asending	J < -0.1	rectilinear	1.0 > s > 0.1
3	HD	horiz / desending	J < -0.1	rectilinear	0.1 > s
4	CC	concave	J < -0.1	basin-shaped	
5	EL	ST elevation relative to resting ECG	0.1 < J		

Arrhythmia

Totally irregular RR distances of normal ventricular complexes are classified as irregular rhythm (absolute arrhythmia).

The following table shows the rhythm disturbances documented by EXEC:

Degree	Abbreviation	Description	Data Recorded
0	-	No obvious rhythm disturbances	-
1	ES	isoltaed VES	Number /Temporal distribution
2	BI	VES as bituminous	Number /Temporal distribution
3	2R	VES as chains of two	Number /Temporal distribution
4	3R	VES as chains of three	Number /Temporal distribution
5	VT	Ventrivular tachycardia	Number /Temporal distribution
6	IR	Irregular rhythm	Time of occurrence

Determination of the Heart Rate

The heart rate is constantly computed from the last eight RR intervals. A beat is however only used for calculation of the heart rate if it is recognized as a normal beat (class 1.2) or if it has the same medical classification as the preceding beat (e.g. with ventricular tachycardia).

Interpretation

The summary report supplied by EXEC will give information about the significance of the test. Apart from information concerning ST abnormalities, the subjective symptoms and causes of interruption are shown.

During the whole of the exercise test, EXEC stores for each lead the ST data with the highest significance and the corresponding maximal ST amplitude (selectable: J00 to J80, J00 to J80 normalized).

ST changes are classified as significant, when the ST classification of degree 2 (or higher) has occurred at least once in a lead, i.e. an ST depression with slow ascending course is already rated as conspicuous.

Determination of the CAD Probability

The EXEC program is equipped with a diagnostic algorithm which provides the physician with a diagnostic statement for patients in whom a diagnosis of coronary artery disease (CAD) is suspected. The CAD probability program is based on the logistic regression analysis technique using both clinical and exercise variables and is designed for use with male as well as female patients without previous myocardial infarction and with a normal resting ECG.

The clinical variables used include age, sex, systolic blood pressure, cigarette smoking, total serum cholesterol (not compulsory) and symptom classification (stratification and definition of symptoms according to the Canadian Cardiovascular Society Classification and the "CASS" registry).

Exercise variables included are heart rate and ST segment amplitude (measured 80ms after J) at rest and at peak exercise.

Calculated probabilities vary between 1 and 99%.

ST - HR Trend Plots

The ST - HR trend plots give a graphical representation of the relationship between the ST variation and the heart rate variation, providing a fairly accurate indication of the seriousness of coronary vascular disease. At the end of every exercise stage, a cross is made on the diagram marking the ST position and the heart rate at that moment.

With increased heart rate, patients with a coronary vascular disease will show an increasing ST depression. There is a trend plot for each lead and these 12 diagrams provide an instant overall view of the changes.

The diagrams are accompanied by a measurement table giving the exact figures in micro Volt x minutes. A measured value is only achieved when all the following conditions are satisfied:

- The ST amplitude is under zero.
- The ST distance drops between measurements.
- The heart rate increases.

The following figures are calculated and given on the table:

- ST - HR slope 1: Slope between last and second last measurement
- ST - HR slope 2: Slope between last and third last measurement
- ST - HR slope 3: Slope between last and fourth last measurement
- dHR: As a reference value, the third heart rate change between the above measurement points is given in beats per minute
- I - V6: Summary of all elevations for all 12 leads
- V1 - V6: Summary of all elevations for the chest leads

NOTE: For the USA, the unit measurement mm is used instead of mV.

WORKING WITH EXEC

When this option is installed the program option is automatically mounted and does not have to be selected as each time you call up exercise testing. EXEC can be used for exercise testing with either a bicycle ergometer or a treadmill.

The settings and adjustments are as described in the relevant User Guide.

Before starting the exercise test some EXEC specific settings have to be made in addition tom those described in the User Guide

These settings contain:

- definition of the ST-Amplitude measurement
- selection of lead for enlarged QRS
- definition of the final report format

Define ST Amplitude Measurement

During an exercise test the ST amplitude is measured continuously. The position of the amplitude measuring point in the ST segment can be chosen freely.

To define these functions go into the exercise setup menu and select the further settings option followed by ST - Amplitude Measurement.

The given temporal distance is measured from the beginning of the ST segment, i.e. the J point. The measurement point can be set to either 00, 10, 20, 30, 40, 50, 60, 70 or 80ms after the J point.

Select Lead for Enlarged QRS Complex

The lead for the enlarged QRS complex - shown on the screen during the exercise test - can be changed with the '+' or '–' keys or the cursor arrow keys.

Define Format for Final Report

Define the format for the final report by entering the exercise menu and selecting the format of the final report option.

ST Trends

Select in the menu:

- **ST-Trends:** Select between YES or NO

If activated with **YES**, the ST trend diagrams are printed out on the third page of the final report. The ST trend diagrams have a time axis of either 30 or 60 minutes depending on the duration of the exercise test.

The trend diagrams are printed for each lead and show the ST amplitude as a solid line and the ST slope as a dotted line. The ST amplitude measurement point and the unit values for both amplitude (mV) and slope (mV/s) are given at the top of the page.

The amplitude measuring at the beginning of the ST segments starts after a defined delay beyond the J point (adjustments see "ST Amplitude Measurements").

NOTE: For the USA, the amplitude values will be given in mm instead of mV.

ST-HR Diagrams

Select in the menu:

- **ST-HR Diagrams:** Select between YES or NO

If activated with **YES**, the ST-HR trend plots are printed out on the fifth page of the final report.

In these diagrams the amplitude variation of the ST segments are shown compared to the heart frequency.

ST Segment Interpretation

Select in the menu:

¶ **Interpretation:** Select between: ST or ----

If activated with **ST**, the ST segment interpretations are printed out on the second page of the final report.

Average Cycles

Select in the menu:

¶ **Average Cycles:** Select between: COMPACT, ALL or – – – – – –

When activated with **COMPACT** or **ALL**, the average cycles are printed out on the seventh to tenth pages of the final report.

With COMPACT the average cycles are printed in four columns in the following order from left to right:

– pretest phase

– maximum load

– begin of rest cycle

– end of rest cycle

With ALL the average cycles are printed for each single step of the exercise test, with data of each load step and the maximum heart frequency at that position.

¶ **Speed:** Select between: 25mm/s or 50mm/s

Rhythm Leads

Select in the menu:

¶ **Rhythm:** Select between YES or NO

With **YES** the printout of the rhythm lead R1 is activated in the final protocol (definition of R1 seethe relevant User Guide "Defining Individual Lead Group").

If a rhythm printout is only desired in the case of rhythm failures, select NO. The rhythm lead R1 can be printed after the test by pressing the **PRINT RHYTHM** key.

¶ **Speed:** Select between: 6.25mm/s or 12.5mm/s

¶ **Sensitivity:** Select between: NORMAL or HALF

The signal sensitivity of the printed lead R1 is either 10mm/mV (NORMAL) or 5mm/mV (HALF).

Define Coronary Artery Disease (CAD) Probability

With this function of the EXEC program, the determination of the probability of coronary artery disease (CAD) can be called up by selecting "CAD Probability" in the main exercise test menu. It is important that all the patient data is started.

IMPORTANT: To determine the probability of CAD two conditions must be met:

– *the patient's birthday must be known (refer to User Guide "Input of Patient Data")*

– *the patient's age, derived from the birthday, must be between 26 and 69 years.*

Data Entry

The menu for the input of data concerning the CAD probability is displayed by entering ther exercise menu and selecting the CAD probability option. Select in the menu:

¶ **Cigarette smoking:** Select between YES or NO

¶ **Cholesterol:** Select between: ——, < 6, 6 – 8, > 8

The cholesterol value is unknown (– – –), less than 6mmol/l (**< 6**), 6 to 8mmol/l (**6 – 8**) or more than 8mmol/l (**< 8**).

¶ **Chest pain:** Select between: non specific, atypical, moderate, severe

¶ **AP during exercise:** Select between YES or NO

With **YES** you confirm that the patient experienced angina pectoris during exercise testing.

Displayed Values

ST/HR Difference (dST/dHR)

The ST/HR difference is shown in the picture in µV*min for the lead V5.

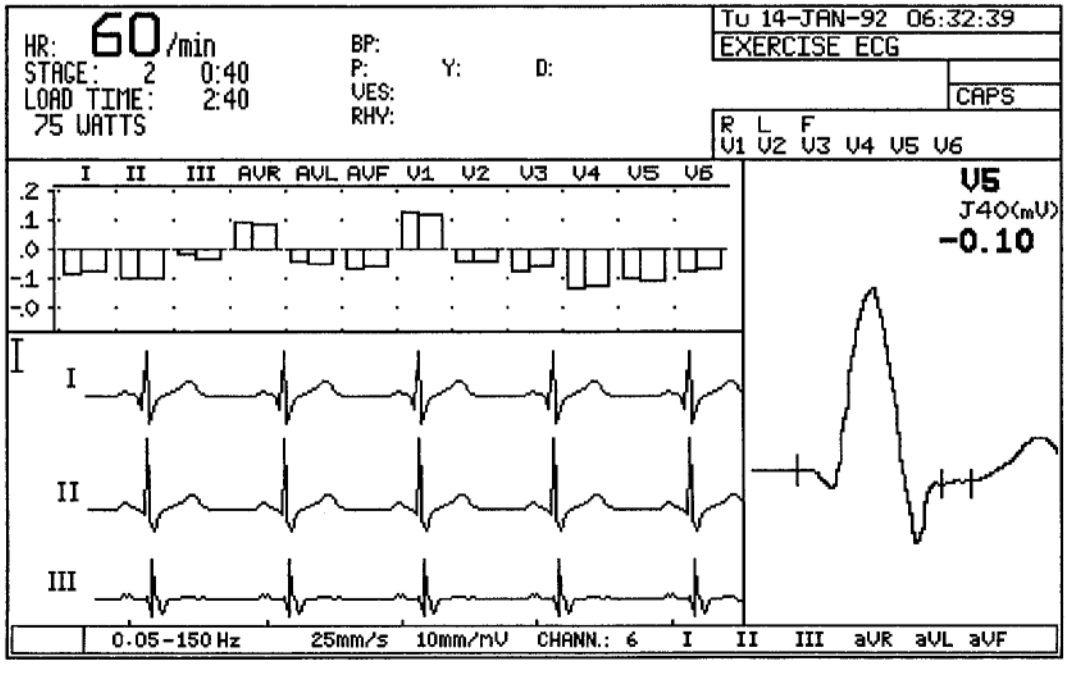
This value is the difference between the ST amplitude during rest and maximum load, divided by the difference between the heart rhythm during rest and maximum load.

CAD Probability Before the Test (pCAD pretest)

This value shows the probability of CAD before the test as a percentage.

CAD Probability After the Test (pCAD post test)

This value shows the probability of CAD after the test as a percentage.



SCREEN PRESENTATIONS

With the EXEC program there are five selectable screen presentations that can be viewed one after the other. The following screens are toggled with the CHANGE SCREEN key:

- Standard Presentation of Exercise Test
- trend plots for blood pressure, load (or speed and elevation) and heart rate
- detailed summary of the occurrences in the extremity leads (ST amplitude trend, ST slope trend)
- summary for the chest leads
- average cycles for each of the 12 leads

Standard Presentation of Exercise Test

Top part of display

On the left the following values are given:

- heart rate
- stage identification and duration
  P = pre-exercise phase
  1...9 = stage number
  R = recovery phase
- total load time (without pre-exercise phase)
- load (bicycle - speed, treadmill - gradient)

This data is continually renewed.

In the centre the following values are given:

- blood pressure
- manually entered symptoms
- number of detected ventricular extrasystoles
- rhythm classification (ventricular tachycardia, bituminous or irregular) (For tests with a treadmill, the current METS value is also given here.)

All this information is permanently displayed regardless of the selected presentation.

Middle part of display

Below the permanently displayed information is a diagrammatic representation of the ST amplitudes for each of the 12 leads.

The block showing the ST amplitude for each lead is divided into two parts.

- The part on the left is for reference purposes and represents the last ST amplitude recorded during the pre-exercise phase.
- The part on the right represents the actual ST amplitude and is continually renewed.

Lower part of display

Below the ST amplitude diagram are three freely selectable leads.

Right part of display

To the right of the screen is the enlarged QRS for the selected lead which is continually renewed.

ANNEX B

PACEMAKER MEASUREMENT

INTRODUCTION

With this software option, the characteristics of a pacemaker can be checked and measured. Both single and dual-chamber pacemaker measurements can be made.

The pacemaker performance is measured between the right arm and the left leg extremity leads.

NOTE: *When carrying out pacemaker measurements, there is a higher risk of electrical interferences. Beware of misinterpretation due to interfering signals!*

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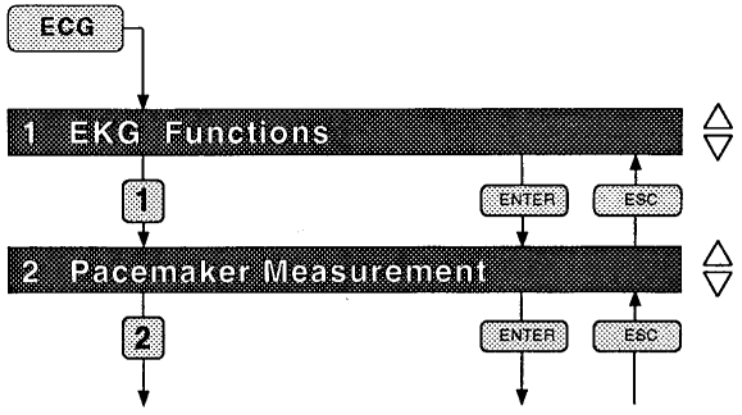
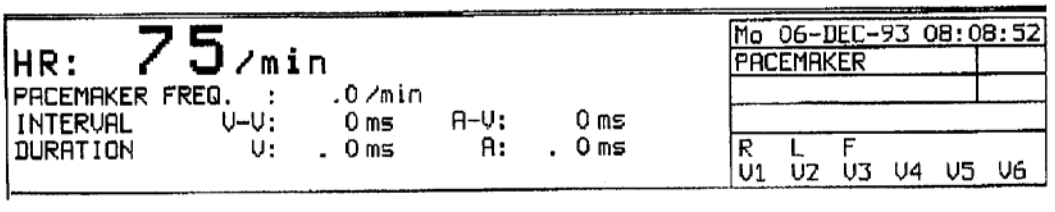
To activate the pacemaker measurements, press the following keys:



By pressing key **2**, pacemaker measurement is activated. Press key **2nd** and **ECG** to deactivate this function.

Displayed Information

When pacemaker measurement is selected, the following information is displayed at the top of the screen:



In the status field at the top right-hand side of the screen, the message "PACEMAKER" indicates that the pacemaker measurement function is active.

The measurements made are displayed in two columns. In the left-hand column the number of stimulations per minute (Pacemaker frequency), the time interval between two stimulations (V-V) and the duration of each stimulation (V) are constantly monitored and updated.

If a dual-chamber pacemaker is being measured, then, in the right-hand column, the time interval between atrium and ventricle stimulations (A-V) and the duration of the atrium stimulation (A) are also given.

Erase Displayed Information

The pacemaker measurements can be removed from the screen by pressing key **2nd** and **ECG**. Otherwise they will remain displayed.

Print Options

To obtain a printout of the pacemaker measurements as displayed on the screen, press the **PRINT SCREEN** key.

As with manual ECG recording, a continuous printout with the pacemaker signals can be obtained by pressing the **MAN START** key. The measurement details, however, are not included. To stop the continuous printout, press the **STOP** key.

Note: Automatic printing is not possible.

ANNEX C

PULMONARY FUNCTION

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INTRODUCTION

There are 4 modes for the measurement and calculation of inspiratory and expiratory values with the spirometry option. For all tests a visual representation of the result is provided along with clearly documented test results. The 4 modes are as follows:

1. Forced Vital Capacity
2. Slow Vital Capacity
3. Expired or Minute Ventilation
4. Maximum Voluntary Ventilation

The spirometry option is simple to operate with easy to follow menu guidance using the normal unit keyboard for data input and test selection. The operating panel of the AT-10 unit provides easy initiation of tests and printouts.

The open pneumotacho sensor is used with disposable mouthpieces and is easily dismantled for cleaning and sterilisation therefore minimizing the possibility of cross-infection.

CARRYING OUT PULMONARY TESTS

Preparation for Pulmonary Function Tests

1 Connect the Flow Sensor

The flow sensor is supplied complete with connecting cable and connection plug.

Insert the plug into the socket marked "SP-110/R" on the unit and tighten the two securing screws. Note that the connecting cable should not be exposed to excessive mechanical stress. Whenever disconnecting the cable, hold the plug and not the cable.

CAUTION: *The flow sensor SP-110 contains a sensitive measuring device and* ***must always be handled with care*** *and not be dropped or subjected to any sudden blows.*

Calibration

IMPORTANT

Calibration must be carried out at the beginning of each day before commencing any tests

2. Connect a calibration pump to the sensor.

3. Press the SPIRO key and select the CALIBRATION option.

Note: The procedure differs for every unit. The procedure detailed here is non specific.

The cursor is positioned at 'temperature'. Enter the ambient temperature and press <ENTER>.

Empty the calibration pump[§]. **Press <ENTER> and at the prompt 'Effective Vol', enter the calibrated volume of the pump, in litres.**

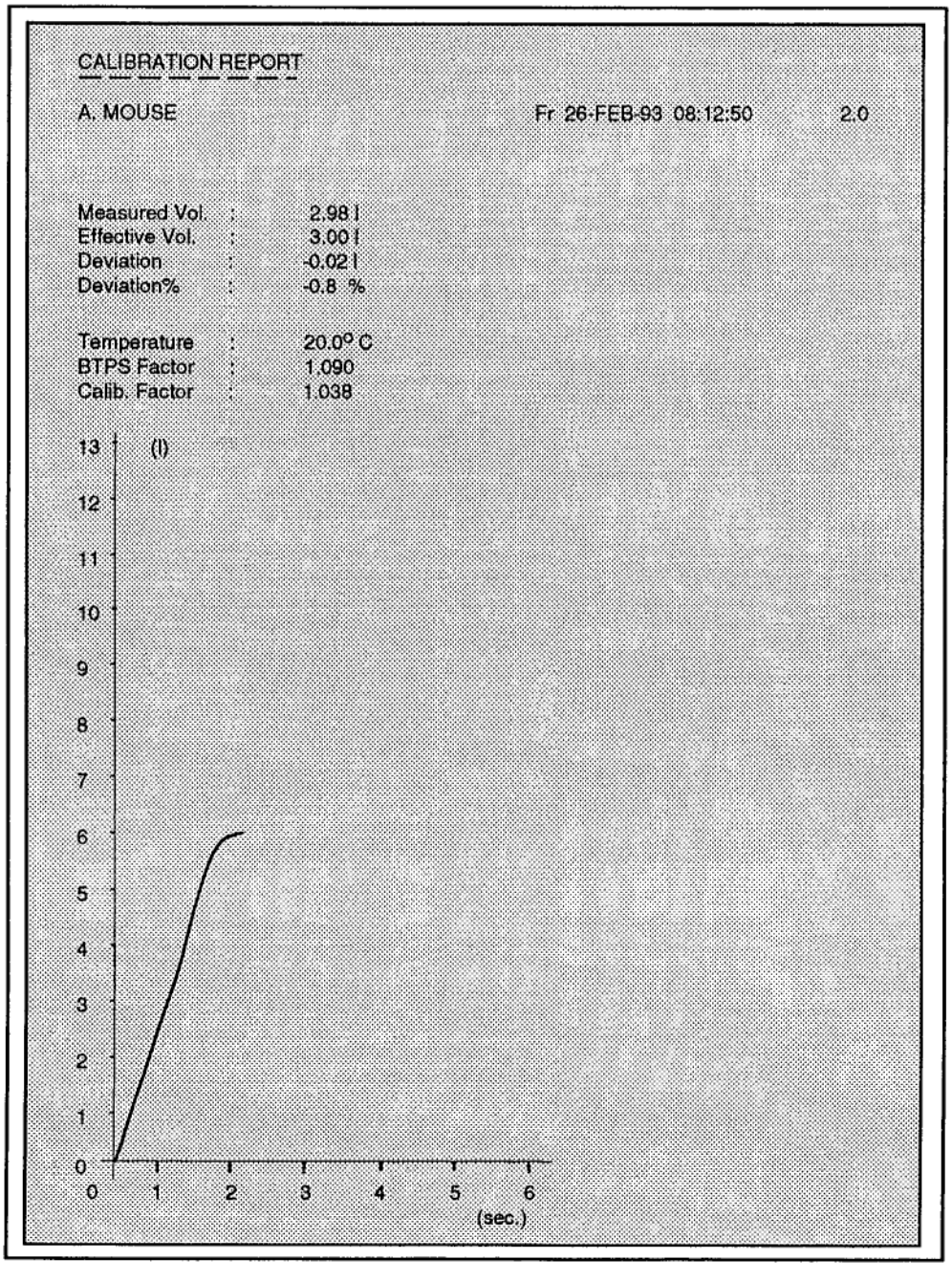
Note: To obtain a more accurate calibration, it is recommended that the calibration pump is emptied more than once to achieve a total volume of more than 6 litres.

Repeat the calibration and ensure that the measured volume is correct. If required a printout of the calibration can be obtained by pressing the <PRINT SEL> key. The printout obtained gives the following data:

Measured Vol:	The calculated volume using the existing calibration.
Effective Vol :	The actual volume received by the unit (that is the calibration pump volume) entered manually by the user.
Deviation:	The difference between the measured volume and the actual volume
Temperature :	The ambient temperature entered by the user

BTPS Factor: The Body Temperature Pressure Saturated factor applied to all subsequent readings (that is, all readings apart from the calibration procedure (as opposed to the ATPS (Ambient Temperature Pressure Saturated))

Calib. Factor: The calibration factor is a software calculated factor which is individually set for the attached transducer and used by the unit in volume calculations



4. Enter Patient Data

Each printout is complete with the name and other information concerning the patient. Before beginning a test, the patient data must be entered.

Press the **PATIENT DATA** key in order to call up the menu for patient data input as follows:

Pat. Name: Patient name (max. 22 characters)

Pat. No.: Patient number (max. 22 characters)

Born: The date of birth has to be entered in figures in the order "day.month.year" separating each with a full stop. For example, for 3rd November 1936, enter "3.11.36" or "03.11.36"

Age: The age is calculated by the unit on the basis of the date of birth.
up to 2 years: Number of months
up to 6 years: Number of years and months
over 6 years: Number of years

Sex: (max. 22 characters, only 1 character necessary: M/F)

Height: Height in centimetres (or in inches for the USA) (max. 3 digits)

Weight: Weight in kilogrammes (or in pounds for the USA) (max. 3 digits)

BP: Blood pressure in mmHg (7 digits) systolic/diastolic: *sss/ddd* or *sss.ddd*

Med: Medication (max. 16 characters)

(rem) Line for remarks (max. 22 characters)

Terminate each entry with **ENTER**. Wrongly typed characters can be deleted with the **DELETE** key. Whole lines are deleted as soon as a character is entered at the first position.

Execution of Pulmonary Function Tests

5. Select the Pulmonary Function Test - Press the SPIRO key and select required test.

The Pulmonary Function Tests that can be carried out with the AT-10 are as follows:

- Forced Vital Capacity (FVC)
- Slow Vital Capacity (SVC)
- Expired or Minute Ventilation (MV)
- Maximum Voluntary Ventilation (MVV)
- Resistance

They all run in a similar way, so that the instructions are valid for all tests. Exceptions are given at the relevant position.

On the left side of the screen each step to perform the pulmonary test is shortly explained.

The right side of the screen shows the menu with the pulmonary functions.

6. Start The Test

NOTE: The flow sensor must be held quite still and no air should be breathed into the device for at least one second before the AUTO START key is pressed.

Press the green **AUTO START** key to start the test.

The message "READY FOR MEASUREMENT" appears on the display. As soon as the patient starts to breathe into the flow sensor, the unit begins to record the expiratory flow and the corresponding curve is represented on the display. An acoustic "beep" indicates when the break-off point for the expiration measurement has been reached. Five seconds afterwards, measurement will be automatically interrupted unless the patient inhales thus initiating the inspiration measurement. Expiration or combined expiration/inspiration measurements will still take place should this break-off point not be reached.

Once the test is completed, the measurement results are calculated and given on the display. When subsequent tests are made, the result with the highest FVC + FEV_1 value will always be saved and given in the right-hand column (MEAS 1).

The result with the lowest FVC + FEV_1 value of the tests already made and stored will be overwritten. An asterisk ("*") indicates the measurement results of the last test made.

Display Presentation

The display indicates the measurements which will be made and gives the predicted results. There are three positions for measurement results enabling several tests to be made.

The coordinates represent the graph on which the curve will be drawn with the respiratory volume in litres being represented on the vertical axes for FVC and SVC tests (the **relative** respiratory volume in litres for **MV** and **MVV** tests) and the time in seconds on the horizontal axis

Interrupt Tests

Any of the following pulmonary function tests can be interrupted at any time by pressing the **STOP** key.

Delete Measurements

The display for each test mode has three positions for measurement results, enabling several tests to be made.

When more than three tests are carried out, the result with the best value will always be given in column 1. The result with the lowest value will be overwritten. The last test made is indicated with an asterisk.

Should you require to delete one of the result columns, press **FNCT** to call up the main menu and then select 'DELETE' from the menu.

To select a particular column for deletion, press the number of that column (i.e. 1, 2 or 3) and that column will be deleted. If you require to delete all the results, i.e. all three columns, then press **4**.

Select Pre-/Post Medication

Each time the Pulmonary Function Testing program is called up, the unit assumes that Premedication tests are to be carried out. This is confirmed by "PRE" which appears in the top left-hand corner of the screen.

In order to carry out post-medication comparison tests, simply select "PRE/POST Med." when in the main menu and "POST" appears in the top left-hand corner by pressing the following keys:

Forced Vital Capacity (FVC) Test

In this test the patient must exhale as quickly as possible from the time of starting the test; be sure that the patient fully understands what is required of him.

If inspiratory measurements are required, the exhalation can be immediately followed by an inhalation. The inspiration results will be given on the printout.

NOTE: The FVC test employs the 'Back extrapolation' method. If the extrapolated volume is too large (>0.1litres or 10% of FVC), then a warning appears on the display and a question mark (?) will appear in the FEV_1 position for that test.

Printout Data

A printout is initiated by pressing the **COPY** key. A menu is displayed giving options to print the best, or all three measurement results.

A printout can be interrupted at any time by pressing **STOP**.

The patient data, the time and date and the standard used for calculation are printed out.

The printout following an FVC test contains the following information:

- FVC curve as shown on the display (expiratory volume as a function of time)
- The flow curve (flow as a function of the respiration volume)
- The measurement results for FVC, FEV, FEF, PEF, and MEF given as actual, predicted (where available), and actual as a percentage of predicted
- The diagnosis (as indication)

Where an inspiration test has also been carried out, the following results are also given:

- FIVC, FIV, PIF and MIF

Slow Vital Capacity (SVC) Test

For this test the patient should breathe normally 3 times and then inhale maximally to total lung capacity and then expire maximally; ensure that the patient understands what is required of him.

Printout Data

A printout can be made of the test by pressing the **COPY** key. A menu is displayed giving the option to print the best or all three measurement results.

A printout can be interrupted at any time by pressing **STOP**.

The patient data, the time and date and the standard used for calculation are printed out.

The printout following an SVC test contains the following information:

- SVC curve as shown on the display (respiratory volume as a function of time)
- The measurement results for SVC, ERV, IRV and TV
- The predicted SVC value
- The actual SVC value as a percentage of the predicted.

If both FVC and SVC tests have been made, then the results from both tests will be included on the same printout.

Expired or Minute Ventilation (MV) Test

This test requires that the patient breathes as normally as possible for up to 60 seconds, but for at least 20 seconds. Make sure that the patient understands what is required of him.

Printout Data

A printout is initiated by pressing the **COPY** key. A menu is displayed giving options to print the best, or all three measurement results.

A printout can be interrupted at any time by pressing **STOP**.

The patient data, the time and date and the standard used for calculation are printed out.

The printout following an MV test contains the following information:

¶ MV curve as shown on the display

¶ The measurement results for MV, RR and TV

Maximum Voluntary Ventilation (MVV) Test

In this test the patient must breathe as deeply and as rapidly as possible over a period of 6 to 12 seconds; make sure that he understands what is required of him.

WARNING: *Extreme care should be exercised when performing this test as there is a danger of hyperventilation.*

¶ MVV curve as shown on the display

¶ The measurement results for MV, RR and TV

If both MV and MVV tests have been made, then the results from both tests will be included on the same printout.

Printed Informations with Post-medication Test

The printout following a post-medication test contains the following information:

¶ Curves of both pre and post-medication tests (the premeditation curve is bold).

¶ The measurement results are shown as the actual results, actual results as a percentage of those predicted, and the percentage change (i.e. difference) from pre to post-medication results.

¶ The diagnosis resulting from the premeditation test is also given on this printout.

NOTE: *The premeditation results used for the comparison printout are those with the highest values, and not necessarily the last made.*

ABBREVIATIONS OF PULMONARY MEASUREMENT

FVC	**Forced vital capacity** The expiration volume achieved by the quickest possible exhalation after a maximal inhalation.
FEV0.5/1.0/3.0	**Forced expiratory volume** The lung volume in litres, measured after 0.5, 1.0 or 3 seconds of forced expiration.
FEF	**Forced Expiratory Flow** The respiratory flow in terms of differing lung volumes measured in litres per second.
$FEF_{25-75\%/75-85\%}$	Flow speed of the expired air by X% of the forced vital capacity (FVC)
$FEF_{0.2-1.2}$	The averaged flow between 0.2 and 1.2 litres of the forced expired vital capacity.
PEF	**Peak Expiratory Flow**
MEF	**Maximum Expiratory Flow**
ERV	**Expiratory Reserve Volume** The possible further expiration starting from the normal expiration level.
IRV	**Inspiratory Reserve Volume** The possible further inspiration starting from the normal inspiration level.
TV	**Tidal Volume** The expirational and inspirational volumes during normal respiration.
SVC	**Slow Vital Capacity** The lung volume measured from a complete expiration following a deep inspiration.
MV	**Expired or Minute Ventilation** The volume of expired air in litres per minute measured over a minimum of one minute.
MVV	**Maximum Voluntary Ventilation** The maximum volume of air which can be moved on expiration while breathing as deeply and as rapidly as possible.
RR	**Respiration Rate**
FIVC	**Forced Inspiratory Vital Capacity** The inspiration volume achieved between a maximal expiration and a maximal inspiration.
$FIV_{1.0}$	The forced inspiratory air volume in litres measured in the first second.
$FIV_{1.0}$ / FIVC	The forced inspiratory air volume measured in the first second as a percentage of forced inspiratory vital capacity.
$FIV_{1.0}$ / FVC	The forced inspiratory air volume measured in the first second as a percentage of forced expiratory vital capacity.
PIF	**Peak Inspiratory Flow** The maximum inspiratory flow speed in litres per second.
$MIF_{50\%}$	Flow speed by 50% of the forced inspiratory vital capacity.

DIAGNOSIS AND STANDARDS

The diagnostic interpretation and the standards used as a basis for the calculation of predicted values is dependent upon the country. For Great Britain, Italy, Spain, Germany and Switzerland, the ECCS and Quanjer standards are used. For Austria the Austrian, for Sweden the Swedish (Berglund) and Quanjer, and in Finland the Finnish and Quanjer.

In India the Indian standards are used and in America the standards used are Knudson, Crapo, Morris and Composite. The American standards are extended with normals taken from the ITS (Intermountain Thoracic Society).

The factors used in the evaluation for diagnosis and the specific standards are automatically included in the respective language software and described below.

Diagnosis for Countries Outside the USA

Possible respiratory problems are diagnosed on evaluation of the following factors:

	%VC	FEV1%
Normal	>80%	>70%
Restrictive	<80%	-
Obstructive	-	<70%
Combined	<80%	<70%

Restrictive Ventilatory Defect is indicated if:

$$\frac{\text{SVC (or FVC)}}{\text{Predicted SCV}} \times 100\% \text{ is smaller than } 80\%$$

Obstructive Ventilatory Defect is indicated if:

$$\frac{\text{FEV1}}{\text{SVC}} \times 100\% \text{ is smaller than } 70\%$$

If both conditions are satisfied, a combined Obstructive/Restrictive Ventilatory Defect is indicated.

Diagnosis for USA and Canada

Possible respiratory problems are diagnosed on evaluation of the following factors:

% Pred FVC	% Pred FEV1	FEV1/FVC	Diagnostic Interpretation
-	<75%	<75%	Low FEV1 suggests obstructive disorder
-	<60%	>=75%	Low FEV1 suggests ventilatory disorder
<75%	-	>=75%	Low FVC suggests restrictive disorder
<60%	-	<75%	Low FVC suggests ventilatory disorder

If both conditions are satisfied, a Combined Obstructive/Restrictive Ventilatory Defect is indicated. In all other cases, the message "Results appear normal" will be given.

Standards for Countries Outside the USA

ECCS

The safety standards of the European Coal and Steel Community Standards (ECCS) are valid for adults of at least 25 years of age. Patients between the ages of 18 and 25 are calculated on the basis of a 25 year old. The calculation equations are as follows:

	Males		Females	
VC	6.103 x H	-0.028 x A -4.654	4.664 x H	-0.024 x A -3.284
FVC	5.757 x H	-0.026 x A -4.345	4.426 x H	-0.026 x A -2.887
FEV1	4.301 x H	-0.029 x A -2.492	3.953 x H	-0.025 x A -2.604
FEV1/SVC	-	-0.179 x A +87.21	-	-0.192 x A +89.10
MEF	1.944 x H	-0.043 x A +2.699	1.252 x H	-0.034 x A +2.924
PEF	6.146 x H	-0.043 x A +0.154	5.50 x H	-0.030 x A -1.106
MEF75	5.459 x H	-0.029 x A -0.470	3.218 x H	-0.025 x A +1.596
MEF50	3.794 x H	-0.031 x A -0.352	2.450 x H	-0.025 x A +1.156
MEF25	2.605 x H	-0.026 x A -1.336	1.050 x H	-0.025 x A +1.107

H = Height in meters

A = Age

Quanjer

The Quanjer and Tammeling comparison is valid for children between the ages of 6 and 17 as follows:

	Boys	Girls
SVC = FVC	1.00 x H2.7	0.95 x H2.7
FEV1	0.84 x H2.7	0.81 x H2.7
FEV1/SVC	0.84	0.84
MEF = PEF	8.2 x H -6.8	6.6 x H -5.3
MEF50	5.6 x H -4.4	4.6 x H -3.3

H = Height in meters

Austria

The Austrian standard values are valid for children between the ages of 7 and 18 and adults between the ages of 19 and 70 as follows:

BOYS	
Average Values	Lowest Level Values
VC = exp (2,786 - 3,08/G + 0,02101 AG)	VC(uG) = 0,82 VC
FEV1 = exp (2,613 - 2,99/G + 0,02080 AG)	FEV(1uG) = 0,81 FEV1
FEV1 %VC = 88,5	FEV1 %VC(uG) = 77,6
MVV = 30 FEV1	MVV(uG) = 0,81 MVV
TLC = (1,388 - 0,077 G) VC	TLC(uG) = 0,80 TLC

GIRLS	
Average Values	Lowest Level Values
VC = exp (3,012 - 3,96/G) A(power 0,2752)	VC(uG) = 0,80 VC
FEV(1) = exp (3,004 - 4,05/G) A(power 0,2666)	FEV(1uG) = 0,80 FEV1
FEV(1) %VC = 91,5	FEV1 %VC(uG) = 82,0
MVV = 30 FEV(1)	MVV(uG) = 0,80 MVV
TLC = (1,388 - 0,077 G) VC	TLC(uG) = 0,80 TLC

FEMALES	
Average Values	Lowest Level Values
VC = - 11,347 + 6,550G - 0,0472AG + 2,0666 lnA	VC(uG) = VC - 0,89
FEV(1) = - 7,527 + 5,251G - 0,0382AG + 1,2777 lnA	FEV(1uG) = FEV(1) - 0,82
FEV(1) %VC = 104,23 - 10,9 lng - 0,478A + 0,00264A(power 2)	FEV(1) %VC(uG) = FEV(1) %VC - 11,3
MVV = 30 FEV1	MVV(uG) = MVV - 24,6
TLC = (1,2413 + 0,0036 A) VC	TLC(uG) = TLC - 1,20

MALES	
Average Values	Lowest Level Values
VC = 12,104 + 8,073G - 0,0406AG + 1,6371 lnA	VC(uG) = VC - 1,16
FEV1 = - 7,205 + 5,997G - 0,0315AG + 0,8745 lnA	FEV(1uG) = FEV(1) - 1,01
FEV1 %VC = 104,42 - 20,87 lnG - 0,315A + 0,001611A(power 2)	FEV(1) %VC(uG) = FEV1() %VC - 11,0
MVV = 30 FEV(1)	MVV(uG) = MVV - 30,6
TLC = (1,134 + 0,0053A) VC	TLC(uG) = TLC - 1,60

G =	Height in meters
A =	Age
uG =	Lowest level
exp =	e-function
n =	natural logarithm

Swedish (Berglund)

The Swedish (Berglund) standard is valid for adults between the ages of 18 and 75 years as follows:

	Males	Females
FEV%	91.79 -(0.373 x A)	92.11 -(0.261 x A)
SVC	1.09 [(4.81 x H) -(0.020 x A) -2.81]	1.09 [(4.04 x H) -(0.022 x A) -2.35]
FEV(1.0)	1.09 [(3.44 x H) -(0.033 x A) -1.00]	1.09 [(2.67 x H) -(0.027 x A) -0.54]

A = Age
H = Height in meters

Finnish

The Finnish standard is valid for adults from the age of 18 years as follows:

Males	
SVC (l)	exp [(-0.00833 x A) + (0.6309 x log A) + (-1.4750 / H) + 0.9047]
FEV1 (l)	exp [(-0.00587 x A) + (0.2756 x log A) + (-1.1655 / H) + 1.0980]
FVC (l)	exp [(-0.00827 x A) + (0.5860 x log A) + (-1.4468 / H) + 0.9461]
FEV1 / SVC (%)	exp [(0.00246 x A) + (-0.3553 x log A) + (0.3095 / H) + 2.1933]
FEV1 / FVC (%)	exp [(0.00240 x A) + (-0.3104 x log A) + (0.2813 / H) + 2.1519]
PEF (l/s)	exp [(-0.00211 x A) + (0.1049 x log A) + (-0.6774 / H) + 1.3255]

Females	
SVC (l)	exp [(-0.01016 x A) + (0.6995 x log A) + (-1.4518 / H) + 0.7763]
FEV1 (l)	exp [(-0.00920 x A) + (0.4772 x log A) + (-1.3284 / H) + 0.9296]
FVC (l)	exp [(-0.00982 x A) + (0.6358 x log A) + (-1.4137 / H) + 0.8320]
FEV1 / SVC (%)	exp [(0.00096 x A) + (-0.2223 x log A) + (0.1233 / H) + 2.1533]
FEV1 / FVC (%)	exp [(0.00062 x A) + (-0.1586 x log A) + (0.0853 / H) + 2.0975]
PEF (l/s)	exp [(-0.00677 x A) + (0.4017 x log A) + (-0.7422 / H) + 0.9661

A = Age
H = Height in meters
log = Log to base 10

Standards for USA and Canada

Morris

The Morris equations are valid for women between 56 and 72 inches tall and within the age range of 20 to 90 years, and for men between 58 and 80 inches tall and within the age range of 20 to 90 years as follows:

	Males	Females
FVC	0.1480 x H -0.0250 x A -4.241	0.1150 x H -0.0240 x A -2.852
FEV1	0.0920 x H -0.0320 x A -1.260	0.0890 x H -0.0250 x A -1.932
FEV1/FVC	-0.3118 x H -0.2422 x A +107.120	-0.0679 x H -0.1815 xA +88.700
FEF(0.2 - 1.2)	0.1090 x H -0.0470 x A +2.010	0.1450 x H -0.0360 x A -2.532
FEF(25 - 75)	0.0470 x H -0.0450 x A +2.513	0.0600 x H -0.0300 x A +0.551
FEF(75 - 85)	0.0130 x H -0.0230 x A +1.210	0.0250 x H -0.0210 x A +0.321

The Morris normals are extended with the following ITS equations:

	Males	Females
FEV(0.5)	0.0831 x H -0.0152 x A -1.914	0.0605 x H -0.0185 x A -0.809
FEV(3.0)	-0.1359 x H -0.0271 x A -3.512	-0.1123 x H -0.0257 x A -2.745
FEV(3.0)/FVC	-0.1593 x H -0.1450 x A +112.090	-0.2380 x H -0.1630 x A +118.160
MVV	3.4040 x H -1.2600 x A -21.400	2.0500 x H -0.5700 x A -5.500

H = Height in inches
A = Age in years

Crapo

The Crapo equations are valid for men between 61 and 77 inches tall and within the age range of 18 to 89 years, and for women between 57 and 71 inches tall and within the age range of 18 to 89 years as follows:

	Males	Females
FVC	0.1524 x H -0.0214 x A -4.650	0.1247 x H -0.0216 x A -3.590
FEV(1)	0.1052 x H -0.0244 x A -2.190	0.0869 x H -0.0255 x A -1.578
FEV(3)	0.1359 x H -0.0271 x A -3.512	0.1123 x H -0.0257 x A -2.745
FEV(1)/FVC	-0.3302 x H -0.1520 x A +110.490	-0.5131 x H -0.2520 xA +126.580
FEF(25 - 75)	**0.0518 x H -0.0380 x A +2.133**	**0.0391 x H -0.0460 x A +2.683**
MVV Vol.	3.4040 x H -1.2600 x A -21.400	2.0500 x H -0.5700 x A -5.500

The Crapo normals are extended with the following ITS equations:

	Males	Females
FEV(0.5)	0.0831 x H -0.0152 x A -1.914	0.0605 x H -0.0185 x A -0.809
FEV(3.0)/FVC	-0.1593 x H -0.1450 x A +112.090	-0.2380 x H -0.1630 x A +118.160

H = Height in inches
A = Age in years

Knudson

The Knudson equations are valid for both children and adults in specific groups according to age and height as follows:

	Males	Females
	H = 44 to 61 inches,	**H = 42 to 58 inches,**
	A = 6 to 11 yrs	**A = 6 to 10 yrs**
FVC	0.1039 x H +0.0 x A -3.376	0.1092 x H +0.0 x A -3.749
FVC(0.5)	0.0760 x H +0.0430 x A -3.050	0.0480 x H +0.0610 x A -1.740
FEV(1)	0.0884 x H +0.0 x A -2.814	0.0853 x H +0.0 x A -2.758
FEV(1)/FVC	-0.2065 x H +0.0 x A +100.439	-0.4849 x H +0.6655 x A +109.974
FEF(25 - 75)	0.0859 x H +0.0 x A -2.320	0.0559 x H +0.0 x A -0.812
PEF	0.1980 x H +0.1660 x A -8.061	0.1240 x H +0.1570 x A -3.920
FEF(50)	0.0960 x H +0.0 x A -2.545	0.0 x H +0.1846 x A +0.736
FEF(75)	0.0434 x H +0.0 x A -1.015	0.0277 x H +0.0 x A -0.166
MVV	3.0300 x H -0.8160 x A -37.900	2.7600 x H -3.4000 x A -108.120
	H = 55 to 76 inches,	**H = 52 to 72 inches,**
	A = 12 to 25 yrs	**A = 11 to 20 yrs**
FVC	0.1499 x H +0.0739 x A -6.887	0.1057 x H +0.0699 x A -4.447
FVC(0.5)	**0.0760 x H +0.0430 x** A -3.050	**0.0480 x** H +0.0610 x A -1.740
FEV(1)	0.1318 x H +0.0636 x A -6.118	0.0892 x H +0.0694 x A -3.762
V(1)/FVC	-0.2065 x H +0.0 x A +100.439	-0.4849 x H +0.6655 x A +109.974
FEF(25 - 75)	0.1369 x H +0.0749 x A -6.199	0.0709 x H +0.1275 x A -2.801
PEF	**0.1980 x H +0.1660 x A -8.061**	0.1240 x H +0.**1570** x A **-3.920**
EF(50)	0.1379 x H +0.1150 x A -6.385	0.0732 x H +0.1111 x A -2.304
FEF(75)	0.1008 x H -0.0057 x A -4.242	
MVV	4.6800 x H +1.8000 x A -192.320	2.7600 x H -3.4000 x A -108.120
For patients over 18 yrs, the following ITS equations apply:		
FEV(3.0)	0.1359 x H -0.0271 x A -3.512	0.1123 x H -0.0257 x A -2.745
FEV(3.0)/FVC	-0.1593 x H -0.1450 x A +112.090	-0.2380 x H -0.1630 x A +118.160
	H = 62 to 77 inches,	**H = 58 to 71 inches,**
	A = 26 to 120 yrs	**A = 21 to 120 yrs**
FVC	0.1524 x H -0.0214 x A -4.650	0.1247 x H -0.0216 x A -3.590
FVC(0.5)	0.0831 x H -0.0152 x A -1.914	0.0605 x H -0.0185 x A -0.809
FEV(1)	0.1052 x H -0.0244 x A -2.190	0.0869 x H -0.0255 x A -1.578
FEV(3.0)	0.1359 x H -0.0271 x A -3.512	0.1067 x H -0.0257 x A -2.745
FEV(1)/FVC	0.0 x H -0.1050 x A +86.686	-0.4704 x H -0.1896 x A +121.678
FEF(0.2 - 1.2)	0.1090 x H -0.0470 x A +2.010	0.1450 x H -0.0360 x A -2.532
FEF(25 - 75)	0.1471 x H -0.0363 x A -4.518	0.0531 x H -0.0344 x A +1.128
FEF(75 - 85)	0.0130 x H -0.0230 x A +1.210	0.0250 x H -0.0210 x A +0.321
PEF	0.2390 x H -0.0350 x A -5.990	0.1240 x H -0.0250 x A -0.740
FEF(25)	0.0900 x H -0.0200 x A +2.726	0.0690 x H -0.0190 x A +2.147
FEF(50)	0.1737 x H -0.0366 x A -5.409	0.0681 x H -0.0289 x A +0.609
FEF(75)	0.0787 x H -0.0230 x A -2.483	0.0244 x H -0.0259 x A +1.118
MVV	3.0300 x H -0.8160 x A -37.900	2.1400 x H -0.6850 x A -4.870
In addition, there are the following ITS equations:		
FEV3.0/FVC	-0.1593 x H -0.1450 x A +112.090	-0.2380 x H -0.1630 x A +118.160

H = Height in inches
A = Age in years

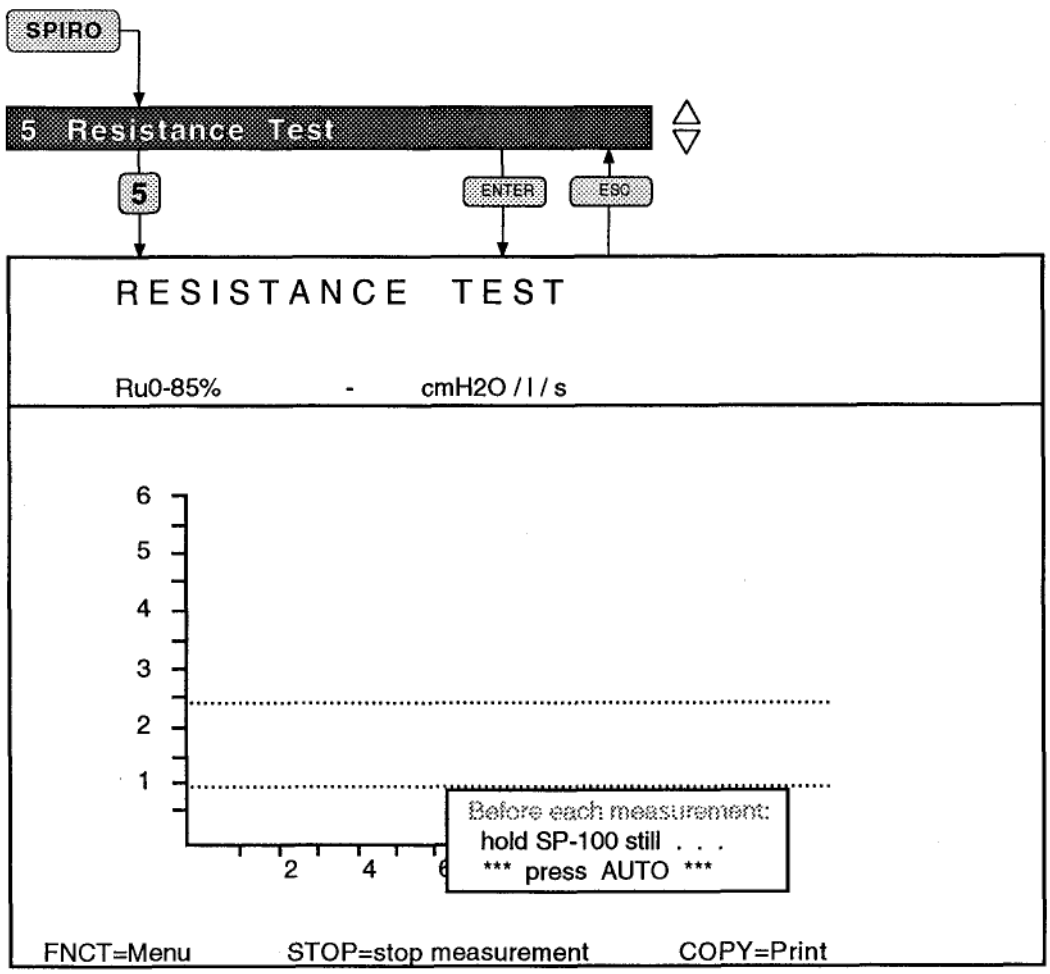
Composite

Selection of the Composite normals provides selected equations taken from other tables as follows:

Value	Equation Reference
FVC	Knudson
FEV(1)	Knudson
FEV(3)	Crapo
FEF(25 - 75)	Knudson
FEF(75 - 85)	Morris
FEF(0.2 - 1.2)	Morris
MVV	Crapo
SVC	Knudson (same as FVC

RESISTANCE MEASUREMENT WITH FLOW SENSOR SP-110/R

Resistance measurement enables the early detection of an obstruction in the respiratory tract through measurement of the lung pressure necessary for exhalation.



Execution of Resistance Test

To call up the expiration resistance test, select "Resistance Test" when in the main Pulmonary Testing menu and the corresponding coordinates appear on the display as in the example given:

The display indicates that an average resistance value will be measured between 0 and 85% of the expired volume of air. To the right, the actual measured resistance will be given as a pressure value in cm H_2O / litre / second. The coordinates represent the graph on which the curve will be drawn with the expiratory flow on the vertical axis and the time in seconds on the horizontal axis.

The patient should inhale as deeply as possible before starting the test and then exhale through the flow sensor in such a way that the curve on the display remains between the two horizontal markers (i.e. between 1 and 2.5 litres). This may require several trial runs before the patient achieves the necessary flow of exhaled air so make sure that he is aware of this and that he understands what is required of him.

NOTE: *At regular intervals during exhalation, the air flow will be interrupted for very short periods. If the air flow is too strong (>2.5 l/s) then the shutter could become blocked and the measurement invalidated.*

Printed Informations with Resistance Test

The printout following a resistance test contains the following informations:

- Resistance curve (resistance as a function of volume)
- The measured pressure as cmH_2O / litre / second

Where an SVC test has also been carried out, the ERV and EV values appear together with the resistance value of the expired volume at ERV.

CARE AND MAINTENANCE

The utmost attention must be paid to the cleanliness of the flow sensor. Because the patients must breathe through the nozzle (inhaling as well as exhaling), it is important that the mouthpiece and filter be renewed and the measuring tube painstakingly cleaned and sterilised before the next patient uses the device.

Cleaning and Sterilising the Flow Sensor

To clean the flow sensor, proceed as follows:

1. Remove and discard the mouthpiece.
2. Remove the rubber adapter by pulling it away from the inner tube.
3. Remove the inner tube of the flow sensor by pushing it out of the outer tube in the direction of the red location marks. Once the tube has been pushed half way it can be pulled out from the other side.
4. Unscrew the two halves of the inner tube and remove and discard the filter.
5. Clean and sterilize all parts of the inner tube, the rubber adapter and the inside of the outer tube with one of the following products:
   - Incidin GG
   - Amocid
   - Lysoformin
   - Alhydex
6. The cable and handle can be wiped with soapy water (do not dip into liquid!).

Reassembling the Flow Sensor

To reassemble the flow sensor, proceed as follows:

1. Insert a new filter into the inner tube so that it sits on the inner lip of the half with the red location mark.
2. Carefully screw the two halves of the inner tube together making sure that the filter is not displaced.
3. Locate the end of the inner tube into the end of the outer tube and push it gently but firmly until the shoulder of the inner tube makes contact on the outside edge of the outer tube. **The two red location marks must be together.**
4. Fit the rubber adapter by placing its wider end over the end of the inner tube with the red location mark.
5. Insert a new mouthpiece (max. 1.5cm) into the end of the rubber adapter.

Cleaning and Assembling the Resistance Sensor

With each resistance test, a build-up of condensation is created within the resistance sensor of the flow sensor. This should be wiped dry after each patient.

To clean the resistance sensor, proceed as follows:

1. Remove and discard the mouthpiece.
2. Disconnect the pressure tube and motor plug from the handle.
3. Pull the resistance sensor out of the rubber adapter.
4. Separate the two halves of the resistance sensor, making sure that the shutter does not fall out.
5. The condensation can now be wiped away with a soft absorbent cloth. The two halves of the resistance sensor and the shutter can also be sterilised with one of the following products:

   - Incidin GG
   - Anocid
   - Lysoformin
   - Alhydex

Assembling

To reassemble the resistance sensor, proceed as follows:

1. Check that the shutter is in place and reassemble the two halves of the sensor making sure that the two air tube apertures are on the same side. Press lightly until the two halves click together.
2. Insert the air tube into the rubber adapter ensuring that the pressure tube and motor plug are on the under side and pointing in the direction of the flow sensor handle (red location mark to the left).
3. Slide the pressure tube over the connection on the handle of the flow sensor.
4. Plug the motor plug into the socket on the handle of the flow sensor.
5. Insert a new mouthpiece.

The resistance sensor is now ready for use.

ANNEX D

LATE POTENTIAL ANALYSIS

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INTRODUCTION

Late potentials are high-frequency, low-amplitude signals at the end of the QRS complex. With an amplitude of about 10µV, these micropotentials are about 100 times smaller than the QRS amplitude (about 1mV). Late potential are therefore not detectable in a normal ECG.

Research has shown that late potentials at the end of the QRS complex may be correlated with an increased risk of ventricular arrythmias and sudden cardiac death.

ANALYSIS OF CARDIAC CYCLES

In order to improve the signal-to-noise ratio, and hence detect late potentials, a series of cardiac cycles (a minimum of 100 is recommended) have to be recorded and averaged for the purposes of analysis and comparison. When examining a patient for late potentials he should be aware that the process demands a certain amount of time and that during the recording he should remain in the recumbent position.

The averaging of about 100 heart beats improves the signal-to-noise ratio by a factor of 10. High-pass filtering of the averaged ECG signals permits high frequency, low-amplitude late potentials to be detected reliably.

CARRYING OUT LATE POTENTIAL ANALYSIS

Analysis Basis

The SCHILLER Late Potential Analysis program analyses the signals either from the data of the 12 simultaneous standard leads (of the normal resting ECG recording) or from the ECG data of the orthogonal Frank XYZ leads.

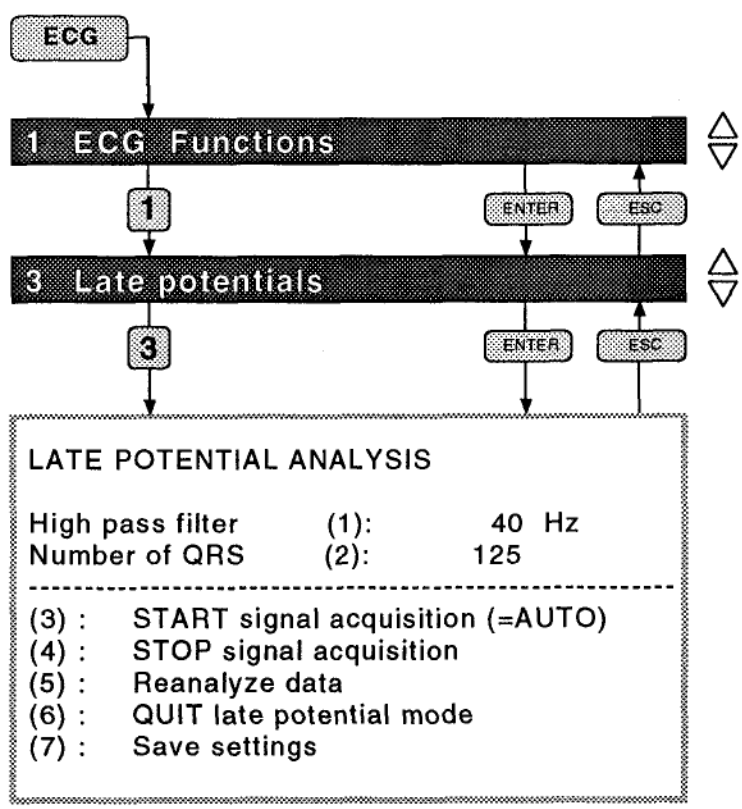
Activate Late Potential Mode

Prerequisites

The electrodes are attached in the correct positions and the required lead configuration (i.e. 12 Standard or XYZ lead) has been selected.

Menu Selections

To access the menu for the late potential analysis, press the following keys:



1. By pressing the number indicated in parenthesis make the following selections:

   - **High pass filter**: (1): Select between: 25Hz
     40Hz
     80Hz
     Key **1** selects the cutoff frequency of the high-pass filter .

   - **Number of QRS**: (2): Select between: 0...300
     in steps of 25
     Key **2** selects the number of QRS complexes to be taken into account for analysis.

2. After the settings have been made, start signal acquisition by pressing key **3**.

   Note: Wait at least 20 seconds after attaching electrodes before pressing key 3 in order to prevent possible baseline wandering.

   During data acquisition, the number of cardiac cycles accepted for averaging (QRS acc.) and those rejected (QRS rej.) together with the actual noise level (Noise µV) are continually updated and displayed at the top of the screen.

3. To stop signal acquisition press key **4**.

   This interrupts data acquisition and starts the automatic analysis. This process is concluded with a printout of the precise analysis results.

Since the data remains in the unit memory, it can be re-evaluated by selecting a new high pass filter setting. Press key 1 to select a new cutoff frequency and then press key **5** (re-analyse data). The results of this analysis will be given in a new printout.

To exit the late potential analysis program without printout of results, press key **6**. Alternatively, press key **2nd** and **ECG.**

Note: Once key **6** has been pressed, the recorded data is immediately erased from the unit memory and is therefore no longer available for further processing or printing.

To save the settings made, press key **7**.

LATE POTENTIAL ANALYSIS REPORTS

The printout at the end of the signal acquisition process comprises 2 pages for the XYZ leads calculated on the basis of the 12 standard leads. The first page provides the late potential results for each of the derived XYZ leads (derived when working with the standard lead configuration in accordance with the Simson method). The second page provides the individual late potential results for each of the 12 leads.

For directly measured XYZ leads (when working with the XYZ lead configuration), one page is printed and provides the standard late potential results for each of the actual XYZ leads.

Signal Presentation

The signal presentation on the printout is as follows (from left to right):

- averaged QRS complex (ranging from 0.05 to 250Hz)
- averaged QRS complex (ranging from the selected high pass filter setting up to 250Hz)
- Vector magnitude for the entire high frequency content of the signal (RMS) across all three XYZ leads

The following indications are given at the bottom of the printout:

- patient data
- noise level during signal acquisition
- number of QRS complexes accepted for averaging (QRS acc) and those not accepted for averaging due to non-correlation (QRS rej)
- heart rate (HR)
- Late Potential analysis results (see below)
- high frequency content of the signal and noise given for each of the actual or derived leads (LAHFd, noise)
- remarks in case of derived XYZ leads (X,Y,Z: derived)

Measurement Results

The following measurement results are given:

- **QRS duration the** duration of QRS given in ms
- **HF QRS duration** the duration of QRS given in ms as determined from the high frequency portion of the signal (starting at the first dotted line and ending at the last dotted line)
- **RMS (40ms)** the root mean square value of the high frequency signal of the last 40ms of the ventricular activation (starting at the dashed line and ending at the last dotted line)
- **RMS (50ms)** the root mean square value of the high frequency signal of the last 50ms of the ventricular activation (starts 50ms before the last dotted line, no marking)
- **LAHFd (40μV)** the duration of the high frequency, low amplitude portion at the end of the QRS cycle (LAHFd = Low Amplitude High Frequency duration, starts at the dotted line which marks the point where the signal drops below 40 μV and ends at the last dotted line)

These results should be evaluated in conjunction with the high frequency averaged QRS complex curves and not in isolation (e.g. look at the curves in order to verify that the beginning and end of QRS have been correctly determined).

The **second** page (when working with the standard lead configuration) provides the individual late potential results for each of the 12 leads. The averaged QRS complex together with the high frequency content is shown for each lead. This report will be useful for the purposes of verifying whether or not the late potential duration is markedly longer in one of the leads than in the vector magnitude.

DATA EVALUATION

Criteria for the Presence of Late Potentials

Frequency range of 25 to 250Hz

According to conventional limits (Simson and McFarlane: The Signal-averaged Electrocardiogram, in "Comprehensive Electrocardiology", Pergamon Press, 1989) the following limits are valid as indication of the presence of late potentials for a signal in the frequency range of 25 to 250Hz:

- QRS duration > 110ms
- LAHFd > 30ms
- RMS-40ms < 25µV

Frequency range of 40 to 250Hz

The following limits are valid for the presence of late potentials for a signal in the frequency range of 40 to 250Hz (G. Breithardt, M. E. Cain, N. El-Sherif, N. C. Flowers, V. Hombach, M. Janse, M. B. Simson, G. Steinbeck: Standards for Analysis of Ventricular Late Potentials Using High-resolution or Signal-averaged Electrocardiography, Journal of the American College of Cardiology, No. 5:999-1006):

- QRS duration > 114ms
- LAHFd > 38ms
- RMS-40ms < 20µV

IMPORTANT: *These criteria do not relate to patients with blocks with a prolonged QRS duration. The noise level after averaging should be lower than 1µV.*

ANNEX E

HEART RATE VARIABILITY

Contents

INTRODUCTION

The SCHILLER RR variability analysis program permits the risk of sustained ventricular tachycardia and of sudden cardiac death to be better accessed by analysing the heart rate regularity(measured between contiguous R waves).

These kind of examinations are usually performed with patients after myocardial infarction, in order to assess the risk of sudden cardiac death, and with diabetics, in order to detect autonomous neuropathy.

Patients suffering from certain diseases show a significantly reduced RR variability. In the past, a 24-hour ECG was required to determine such a reduced RR variability. With the SCHILLER analysis program, it is now possible to determine the RR variability by measuring either 512 or 1024 heart beats (i.e. within 10 to 20 minutes).

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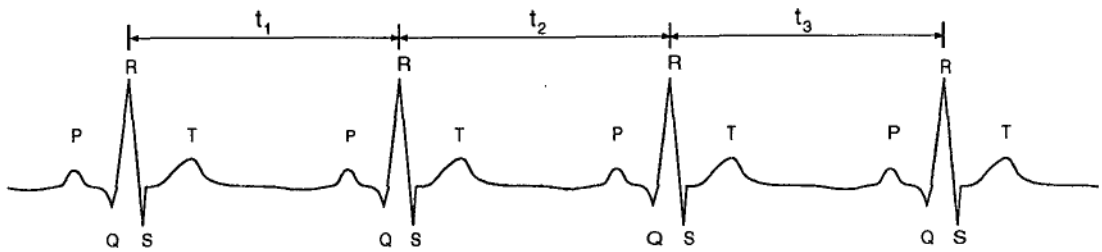
BASICS OF HEART RATE VARIABILITY

The heart rate is not a permanently constant value, but variable within certain limits; a completely regular heart rate may even be considered pathological.

In order to measure heart rate variability, RR intervals are determined during sinus rhythm, in periods without rhythm disturbances (see intervals t_1, t_2, t_3 ...).



Heart rate regularity is, among other factors, influenced by the sympathetic and parasympathetic nerves (e.g. by the autonomous nervous system) which regulate physiological variations in the body.

Sinus node and therefore heart rate are stimulated by the sympathetic nerve and inhibited by the parasympathetic nerve. A further important factor influencing RR variability (heart rate variability) is respiration.

Respiration

During inspiration, the RR interval is decreasing (i.e. heart rate is increasing), during expiration, the RR interval is increasing (i.e. heart rate is decreasing). This physiologically normal variation of the RR interval is called respiratory arrhythmia, showing the highest extent with children and decreasing with age.

Further Factors

Apart from respiration, further factors such as varying arterial blood pressure and psychical and physical condition of the patient also influence the heart rate.

In order to exclude influence on RR variability by physical stress or emotions, the patient should relax completely during examination.

RESULTS FROM LONG-TERM ECG EXAMINATIONS

According to studies on long-term ECG examinations, the risk of death from sudden cardiac death after myocardial infarction is five times higher for patients with a RR variability below 50 ms than for patients with a higher variability. A reduced RR variability therefore indicates an increased risk of sudden cardiac death (similar to the detection of ventricular late potentials). A reduced RR variability in patients suffering from cardiac diseases also indicates a high risk for sustained ventricular tachycardia.

Furthermore, the determination of heart rate variability (especially the frequency analysis) permits assessment of the balance between sympathetic and parasympathetic nerve.

This balance is disturbed not only in patients suffering from cardiac diseases, but also in diabetics with autonomous neuropathy. These diabetics - similar to patients susceptible to death from sudden cardiac death - show a significantly reduced RR variability.

FREQUENCY ANALYSIS

Signals in the Frequency and Time Range

A cosine signal in time domain is characterised by its amplitude A_1 and the time interval T_1 between two maximal values (period of oscillation T_1) (**Fig 1a**).

This signal cannot only be presented in time domain, but also in the frequency domain. Frequency f is defined as indirectly proportional to time t: $f = {}^1/t$.

The cosine signal in frequency domain is therefore presented as (delta) peak with amplitude A_1 and frequency ${}^1/T_1$ (**Fig 1b**).

The cosine signal with a lower amplitude A_2 and a shorter period of oscillation T_2 (**Fig 2a**) is shown in frequency domain as peak with frequency ${}^1/T_2$ ($A_1 > A_2$, $T_1 > T_2$ and ${}^1/T_1 < {}^1/T_2$) (**Fig 2b**).

When both signals are summed (**Fig 3a**), two spectral lines result at the points ${}^1/T_1$ and ${}^1/T_2$ (**Fig 3b**).

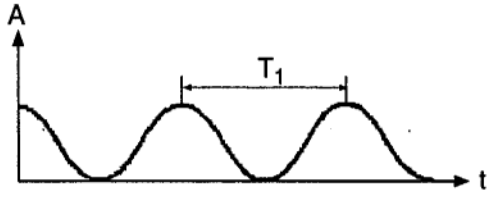


Fig. 1a
Cosine signal in the time

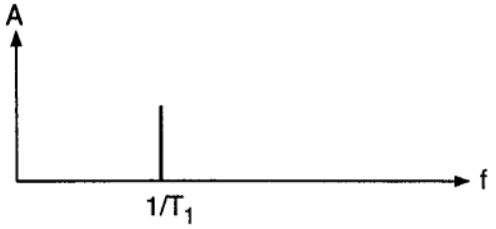


Fig. 1b
and frequency domain

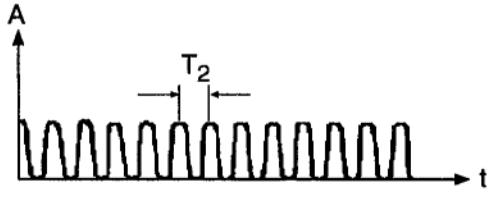


Fig. 2a
Cosine signal in the time

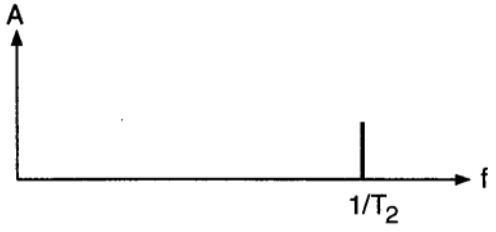


Fig. 2b
and frequency domain

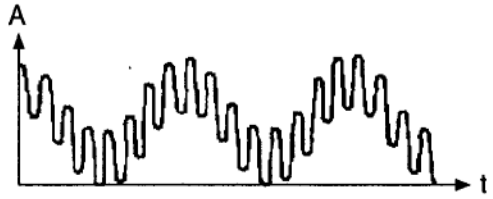


Fig. 3a
Sum of the signals of Fig.1 and Fig. 2 in the time

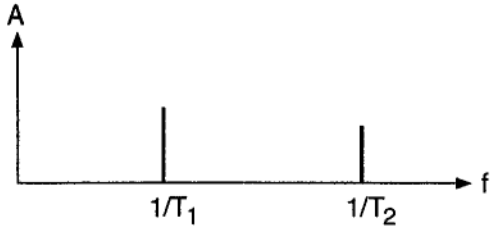


Fig. 3b
and frequency domain

Transformation from Frequency to Time Domain

The Fourier Transformation

Every arbitrary signal may be presented not only within time, but also within frequency domain, i.e. as sum of various cosine functions with different amplitudes (**Fig 4a/b**).

A transformation from time to frequency domain is performed by means of the so-called Fourier Transformation.

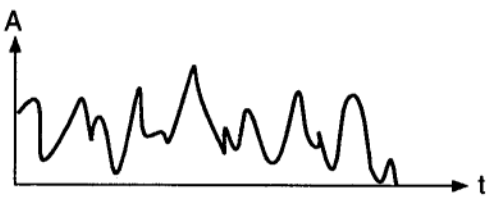


Fig. 4a
Arbitrary signal in the time

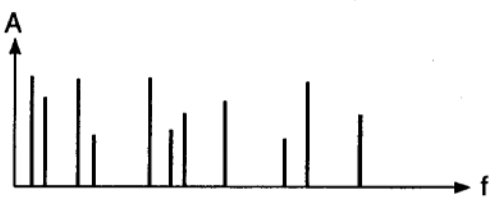


Fig. 4b
and frequency domain

A fast type of the Fourier Transformation is the so-called Fast Fourier Transformation (FFT), that calculates a Fourier Transformation with a number of sample values corresponding to a power of 2. In order to perform FFT, SCHILLER analysis examines either $512 = 2^9$ or $1024 = 2^{10}$ RR intervals.

Performance of the Fourier Transformation

Some signal characteristics are easier to detect in frequency than in time domain. Examinations on oscillation characteristics of motors are e.g. performed with Fourier Transformation, as indications of wear can be detected at an early stage from changes in the Fourier spectrum.

Furthermore, **pathological changes of the heart** can be detected in Fourier Transformation of RR intervals.

In practice no endless periodical signals are examined (**Fig 5a/b**), but time limited non-periodical signals (**Fig 6a**). Fourier Transformation of these time limited signals does not provide individual delta peaks as described above, but blurred peaks decreasing in an oscillatory manner to the right and to the left, producing the so-called sidelobes (**Fig 6b**).

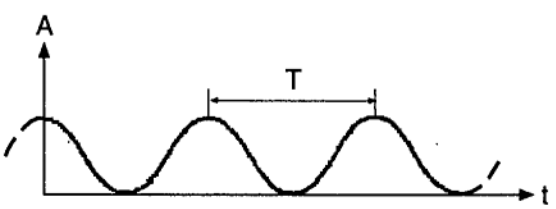


Fig. 5a
Endless periodical signal in the time

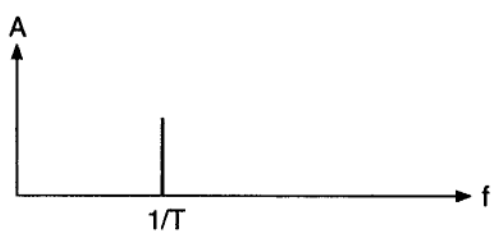


Fig. 5b
and frequency domain

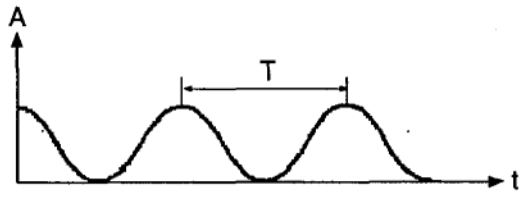


Fig. 6a
Time limited signal in the time

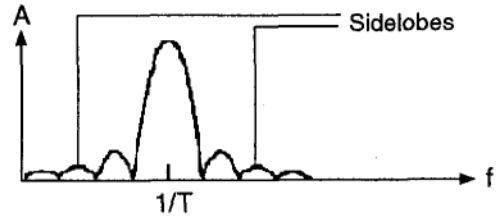


Fig. 6b
and frequency domain

Time Limitation of Signals (Windowing)

Usual time limitation (i.e. full signal amplitude up to the point of limitation, otherwise signal amplitude equals zero) can be imagined as windowing of an endless signal (**Fig 7a**) with a rectangle function (**Fig 7b**), speaking of a rectangular window function.

Endless periodical signal superimposed with a rectangular window

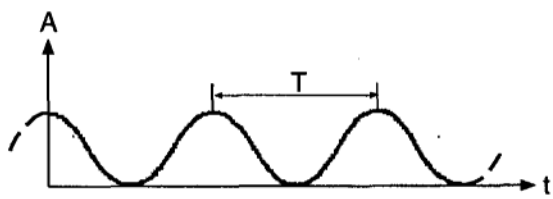


Fig. 7a
An endless periodical signal superimposed

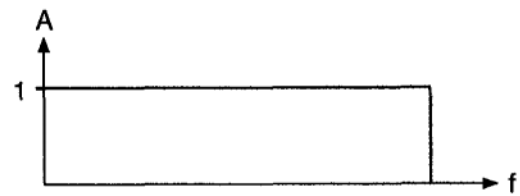


Fig. 7b
with a rectangular window

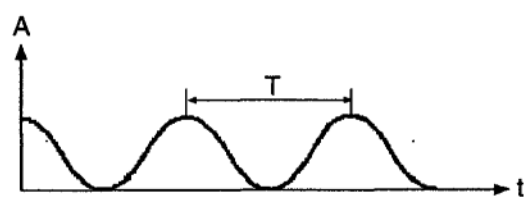


Fig. 8a
results in a time limited signal in the time

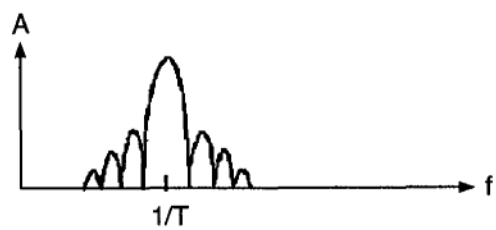


Fig. 8b
and frequency domain.

Such a rectangular window function, however, produces sidelobes with relatively high amplitudes (**Fig 8b**).

Optimal Window Types

Cutting off the signal not abruptly, but gradually, e.g. by windowing the signal with a cosine-like function (**Fig 9b**), provides side lobes with lower amplitudes, but extended main lobes (**Fig 10b**), as compared to the rectangular window type.

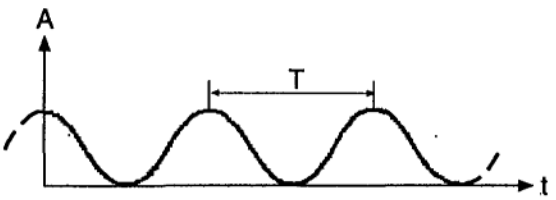


Fig. 9a
An endless periodical signal superimposed

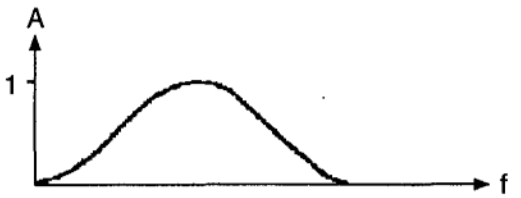


Fig. 9b
with a cosine window

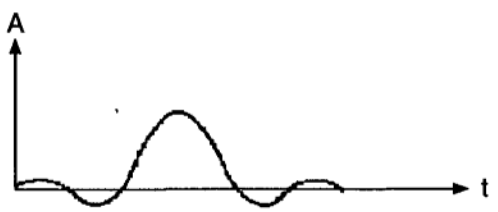


Fig. 10a
results in a time limited signal in the time and

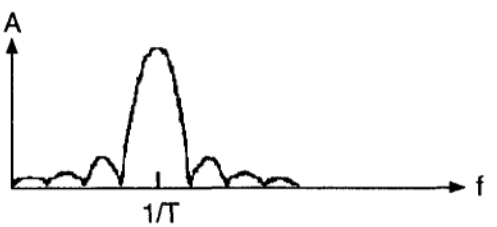


Fig. 10b
frequency domain.

Optimal window types, minimising the disadvantages of high sidelobes and extended main lobes, are the cosine-like **Hanning** and **Blackman-Harris** window types.

Standardisation

Before performing Fourier Transformation of RR intervals, they are standardized according to different procedures. Calculation mode performed is determined in the menu "Heart Rate Variability", item "FFT Type".

For:

x(i) = value x, calculated from the *ith* RR interval submitted to FFT

RR(i) = *ith* RR interval

RRaverage = average RR interval

(1/RR) average = average calculated from the reciprocal values 1/RR of RR intervals

RR intervals are transformed as follows :

$$\textbf{1.}\ x(i) = \frac{RR(i) - RRaverage}{RRaverage}$$

$$\textbf{2.}\ x(i) = RR(i) - RRaverage$$

$$\textbf{3.}\ x(i) = \frac{1/RR(i) - (1/RR)average}{(1/RR)average}$$

$$\textbf{4.}\ x(i) = 1/RR(i) - (1/RR)average$$

Fourier Transformation is finally applied to the values x(i), and their FFT spectra are analysed within various frequency ranges.

Analysed Ranges

The FFT spectra are analysed within the following frequency ranges:

0.016 Hz to 0.05Hz,

0.05Hz to 0.15Hz

0.15Hz to 0.35Hz.

A reduced influence of the parasympathetic nerve can be detected on a reduction of the high frequency signal portion, whereas an increased influence of the sympathetic nerve results in an increase of the low frequency signal portion.

Both variations in the autonomous nervous system may influence electrical stimulation conduction within the heart, resulting in **an increased risk of continuous tachycardia and sudden cardiac death.**

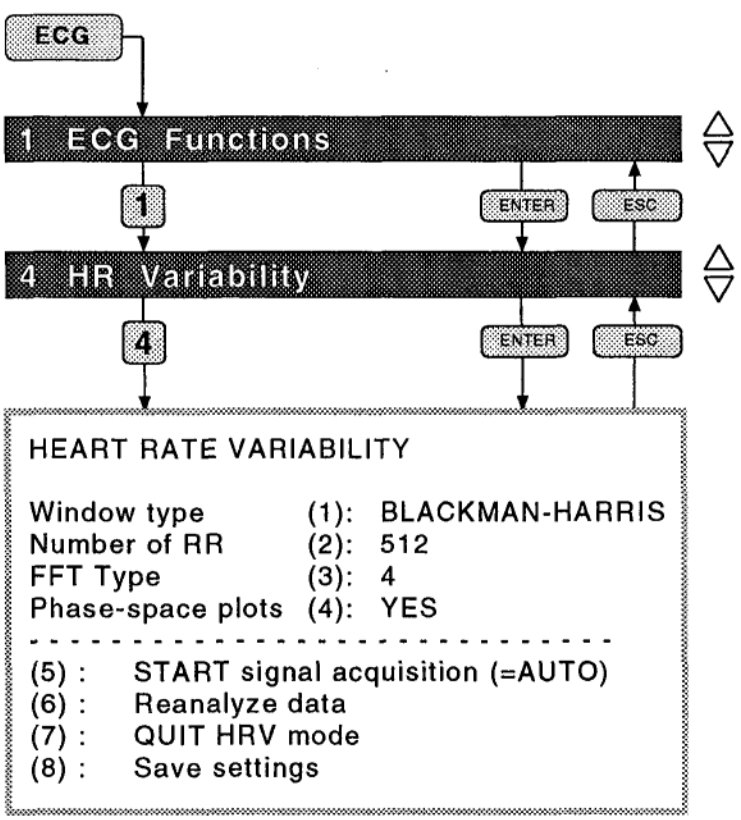
EXECUTION OF THE RR ANALYSIS

Before the Analysis

Before starting the measurement the following parameters can be selected:

- FFT window type (type of signal limitation in time domain before Fourier Transformation: rectangular, Hanning, Blackman-Harris window type
- number of RR intervals to be measured (512 or 1024)
- FFT type (type of preparation and standardization of RR intervals before Fourier Transformation is applied). see "Frequency Analysis" later in this chapter.
- Phase-space plots (option for the printout). see "Phase-space plots" later in this chapter.

To measure the heart rate variability, press the following keys:



To activate the analysis program proceed as follows:

1. Make following selections in the menu:

- **Window Type**: (1): Select between: RECTANGULAR, HANNING, BLACKMAN-HARRIS
- **Number of RR**: (2): Select between: 512, 1024
- **FFT type**: (3): Select from: 1 to 4 - this selects the calculation mode for the fourier transformation.
- **Phase-space plots**: (4): Set to YES or NO. Select YES to printout the phase space diagram or NO to suppress the printout.

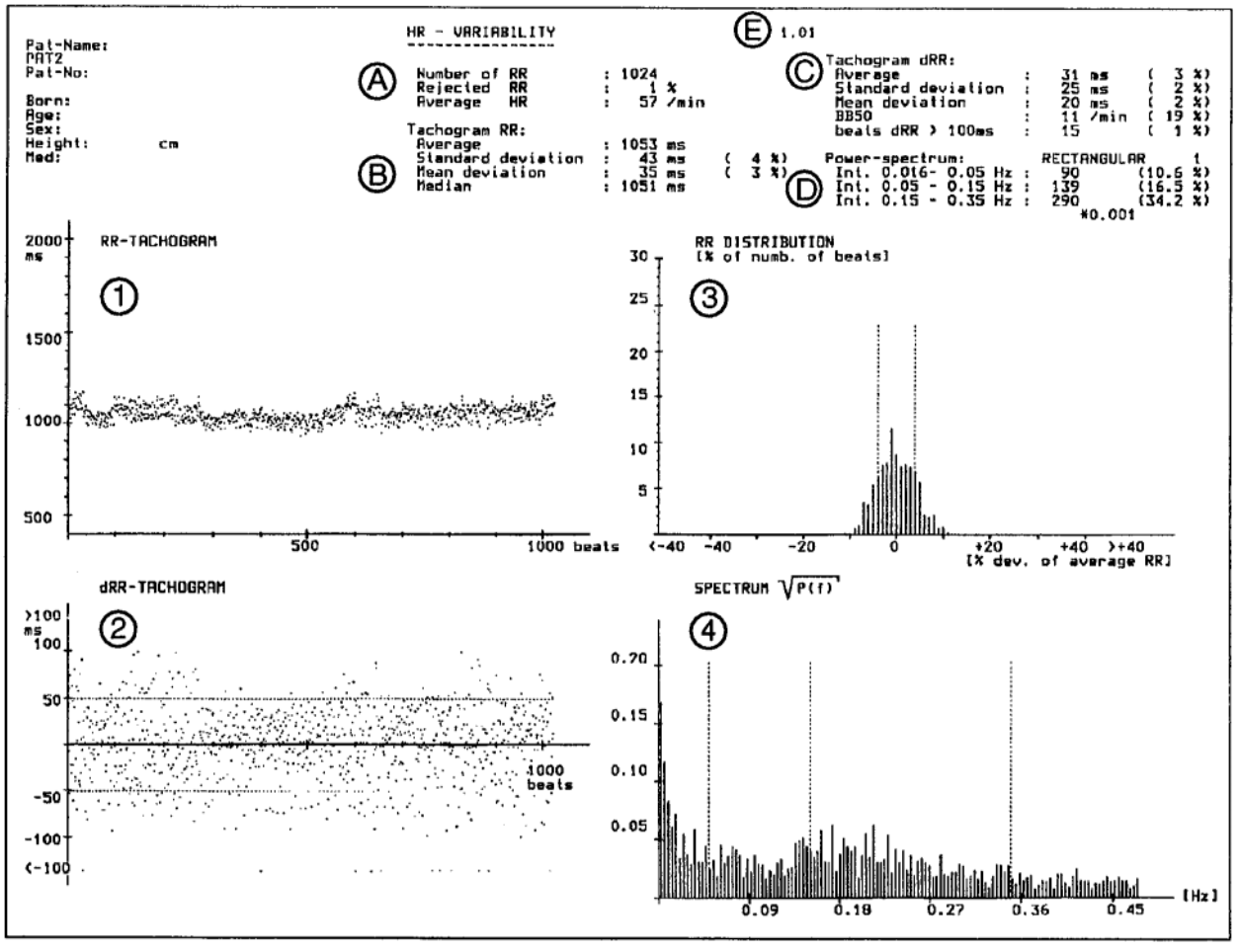
2. Start the signal acquisition by pressing key **5. During** signal acquisition, the number of intervals accepted for the analysis is displayed in the upper part of the screen. Once the predefined number of RR intervals has been evaluated for analysis, the printout is initiated.

As long as the data is in the memory, different window types can be selected for further calculations. Select a new window type (press key **1** for **Window Type**) and press key **6** (Reanalyze data). The results of this analysis will be printed out.

With the key **7,** the RR variability program can be quit without any printout.

To save the settings made, press key **8**.

RESULTS



The software version of the RR analysis program is indicated at Ⓔ.

Ⓐ *Settings*

- Number of measured RR intervals (512 or 1024)
- Percentage of rejected RR intervals (after triggering, correlation found too low)
- Average heart rate (in beats per minute

① *and* Ⓑ *RR Tachogram*

- RR interval (Y axis in ms) for the examined heart beat (X axis, number of beats)
- **Average value m**

  $m = {}^{1}/_{n} * (t_1 + t_2 \ldots\ldots + t_n)$ of examined RR intervals $t_1, t_2, \ldots\ldots, t_n$
- **Standard deviation s** of these RR intervals

  $s = \sqrt{8}\ {}^{1}/_{(n-1)} * ((t_1 - m)^2 + (t_2 - m)^2 + \ldots + (t_n - m)^2))$
- **Average (absolute) deviation d**

  $d = {}^{1}/_{n} * (|t_1 - m| + |t_2 - m| + \ldots\ldots + |t_n - m|)$
- **Median** 50% of all values are above and 50% below this value. In a symmetrical distribution this value equals average value. If the two values do not correspond to each other, the distribution of the RR intervals is not symmetrical.

All values are also indicated as percentage of the average RR interval.

② And Ⓒ dRR Tachogram

The diagram at shows the **difference** of the RR intervals between contiguous heart beats, i.e.:

$dt_1 = t_1 - t_2$ (Difference between the first and second RR interval)

$dt_2 = t_2 - t_3$ (Difference between the second and third RR interval)

$dt_3 = t_3 - t_4$ (Difference between the third and fourth RR interval)

These difference (delta) values (in distinction to RR, here called dRR) are presented in the graph dependent upon the number of heart beats. The limit value in the graph is 50ms.

For the statistical interpretation the following are given:

- Average values
- Standard deviation
- **Average deviation** of RR variability
- **BB50** (beat-to-Beat-50ms) Number of beats with a beat to beat difference exceeding 50ms.

  The lower the BB50 value, the higher the extent of pathology in diagnosis.

- **Beats dRR > 100ms** Number of beats with variability exceeding 100ms. Information is also given in percents of the average RR interval.

③ Frequency Distribution

Frequency distribution of RR intervals examined, with reference to the average RR interval (indicated at x = 0), and percentile deviations.

The dotted lines mark standard deviations. According to Gauss, in normal distribution, 68 % of all values remain within the value range of this double standard deviation. The graph also shows to which extent distribution of RR intervals is symmetrical.

④ and Ⓓ Frequency Spectrum

After frequency analysis (with Fast Fourier Transformation FFT), distribution of RR intervals is presented within frequency domain (and no longer within time domain, as before). Influences from the autonomous nervous system by the sympathetic or the parasympathetic nerve may be distinguished, and any disturbances in their mutual balance detected.

Spectral high frequency limit is:

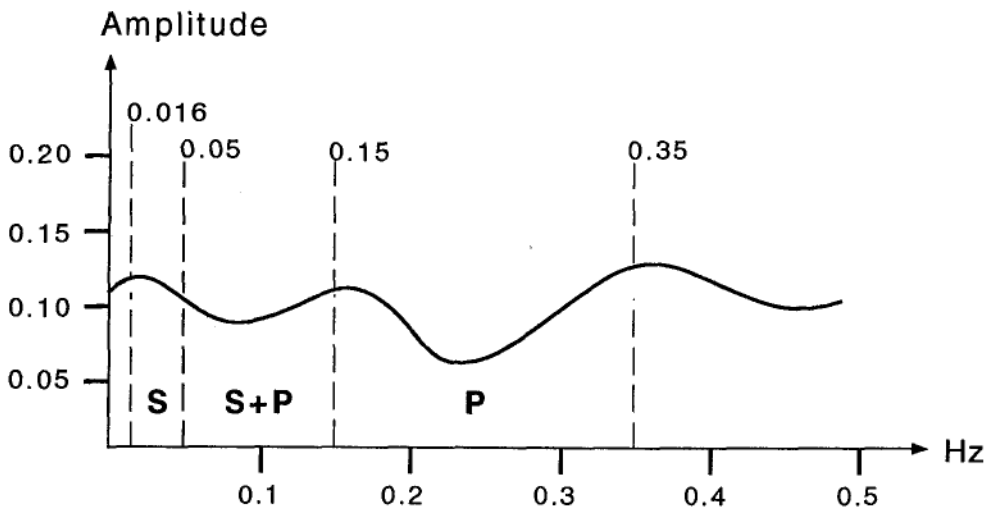
$$\frac{1}{2 * (\text{average RR interval})}$$

For frequencies above 0.15Hz, the influence from the sympathetic nerve on RR variability is negligeable.

The frequency spectrum in this high frequency range is mainly determined by the activity of the parasympathetic nerve. Between 0.05Hz and 0.15Hz, parasympathetic and sympathetic influences may be found.

Below 0.05Hz, influence of the parasympathetic nerve is significantly weaker than in high frequencies, whereas the sympathetic influence reaches its highest extent in low frequency ranges. An inhibition of the parasympathetic nerve therefore shows in a reduction of high frequency spectral ranges.

The following illustration shows a simplified presentation of frequency dependent effects by sympathetic (S) and parasympathetic (P) nerves.



Within these three frequency intervals (S, S+P and P), influences of sympathetic and parasympathetic may be assessed from the area (integrals) of the FFT spectrum.

These areas are indicated with the data from as percentage values with respect to the total area of the FFT spectrum:

- **Int. 0.016 to 0.05Hz** (Frequency interval S)
- **Int. 0.05 to 0.15Hz** (Frequency interval S+P)
- **Int. 0.15 to 0.35Hz** (Frequency interval P)

Notes: In comparing data from various patients, percentage indications should be compared - **not** the absolute values, as spectral energy depends upon the individual patient.

Age dependent standard values for RR variability have up to present not been considered neither in time nor in frequency analysis.

PHASE-SPACE PLOTS

In addition to the statistical analysis of the RR-variability (such as the calculation of a mean value, standard deviation, absolute deviation, RR-tachogram and RR-histogram) and the frequency analysis (FFT analysis with 512 or 1024 RR intervals with selectable window types and standardization procedures), the program offers the **phase-space plots** as a further evaluation form of the RR variability. This analysis also considers, for the first time, the chaotic property of the heart.

In the exploration of heart rate variability it has been indicated that mathematical methods of chaos theory considered for heart rhythm give further evidence of high risk of sudden cardiac death.

In this chaos theory (of deterministic chaos), complex systems with many interacting components are analysed. The interaction is non-linear, i.e. the change that a component effects, does not have to have the same size-order as the component itself. In other words: small changes in one component can effect very large changes in the system.

According to the latest studies, the heart, being a complex of many varying cells with its multiple influences from the central nerve system, reacts as a non-linear chaotic system.

The Fundamental Calculation of the Phase-space Plots

In the phase-space plot of the heart rate variability, the chaotic aspect of the heart rhythm is considered. Therefore you look at successive RR intervals during sinus rhythm:

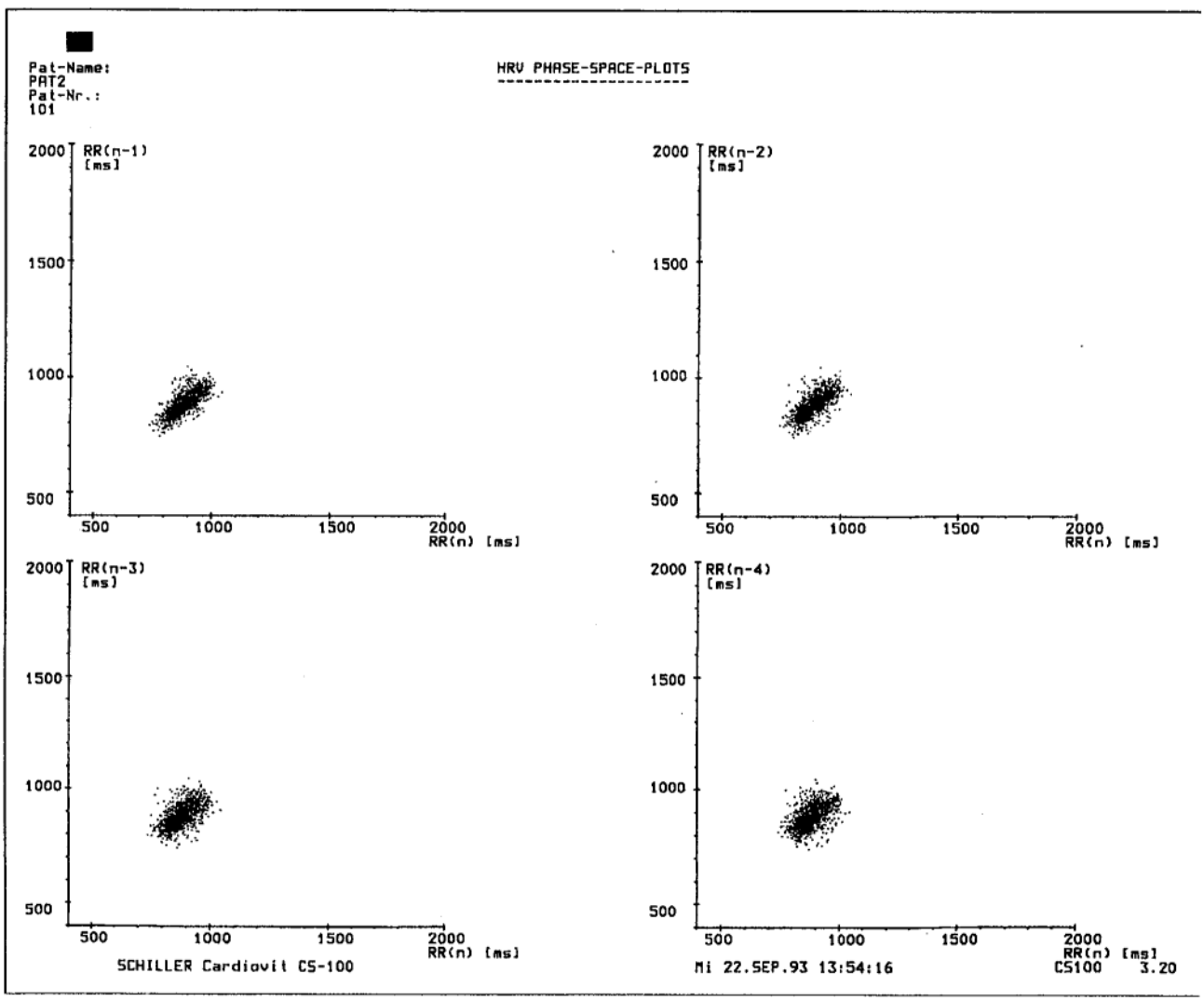
RR(1) is the first RR interval (between the first and the second R peak)

RR(2) is the second RR interval (between the second and the third R peak)

RR(3) is the third RR interval (between the third and the fourth R peak).

Phase-space Diagram - Printout

The phase-space plot being the second page of the RR variability evaluation looks as follows:



Phase diagram of a person with a healthy heart

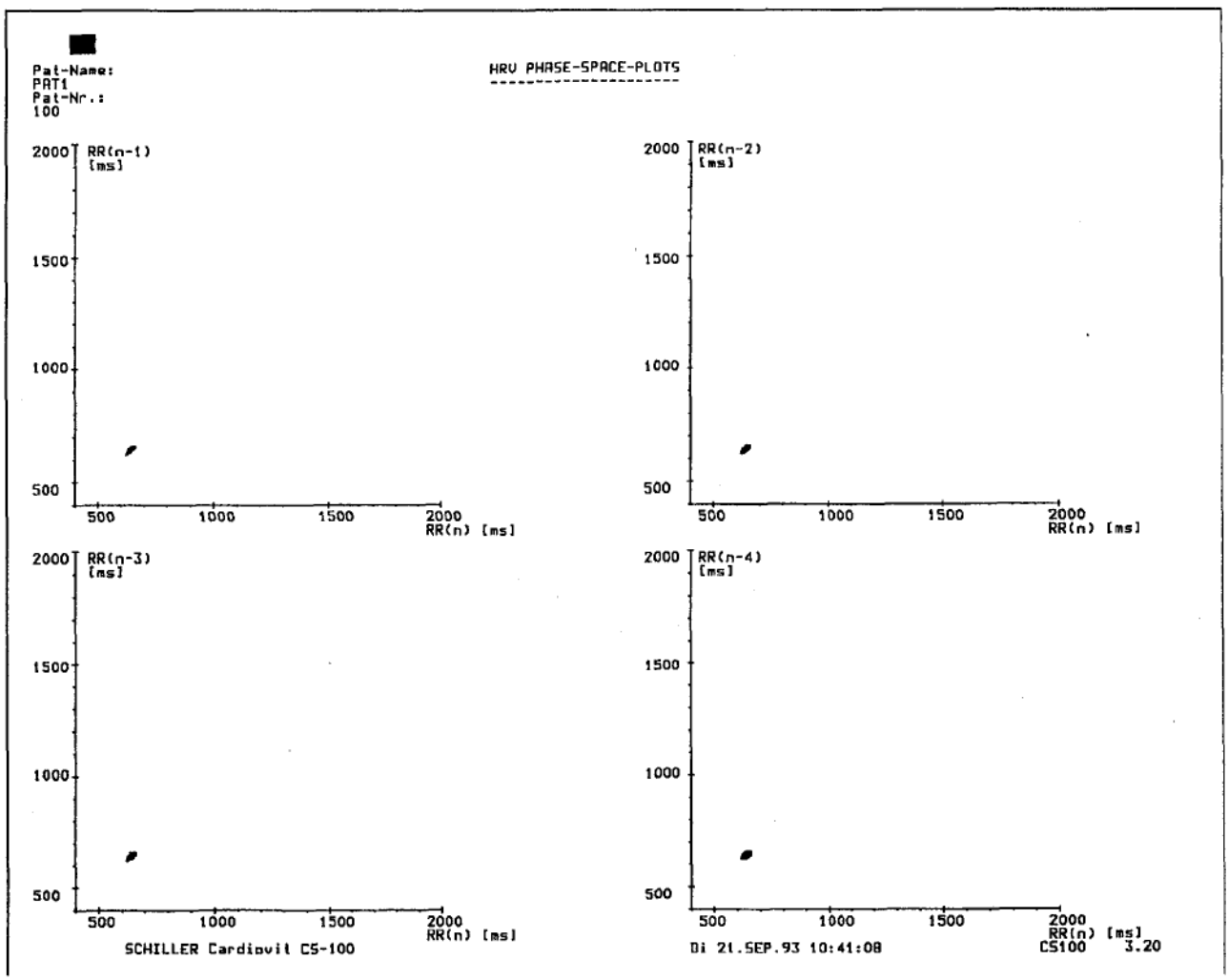
In the two-dimensional phase diagram, RR(2) is shown as the x-component and RR(1) is shown as the y-component of point (RR(2), RR(1)). The next point shows as x-coordinate RR(3) and as y-component RR(2). Generally the nth RR interval is represented on the x-axis and the (n-1)-th RR interval on the y-axis.

The phase diagram **top left** shows the correlation in rhythm between successive RR intervals. On the **top right** there is the correlation between one RR interval to the RR interval after the next (i.e. a distance of two RR intervals), **bottom left** shows the correlation between RR intervals that are three RR intervals apart and on the **bottom right**, there is the correlation of RR intervals with a distance of four RR intervals.

The total of all possible phase diagrams (endless!) forms the so-called multiple-dimensional phase-space diagram. The described representation only gives a fraction of this phase space.

The shape of these point-like clouds gives, according to latest studies, probably a standard for a patient's risk of sudden cardiac death. The above figure shows the phase diagram of a person with a healthy heart. In the cigar-shaped point-like clouds of a healthy person, one can see that this heart moves (within certain limits) between larger and smaller RR intervals, thereby reacting to physiological changes in the body.

The following phase spot plots of a patient with coronary artery disease shows a rigid heart rhythm. This patient has a very high risk of a sudden cardiac death. His heart cannot adapt to physiological changes in the body and therefore it is more likely to "completely loose its rhythm" under certain conditions, causing ventricular fibrillation and sudden cardiac death.



Phase diagram of a person with coronary artery disease

How far certain patterns in the phase-space plot can identify patients with a very high risk of sudden cardiac death, will have to be determined in further studies. Further mathematical analyses (such as dimension determination of the attractor in the phase space) will supplement graphic representation of the phase space in the future, and enable exact statements about the risk of a sudden cardiac death and about therapy effects.

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